INTERNATIONAL STANDARD

ISO 80601-2-12

Second edition
2020-02

Medical electrical equipment —

Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

Appareils électromédicaux —

Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs

Reference number
ISO 80601-2-12:2020(E)

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electric equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-12:2011), which has been technically revised. It also incorporates the Technical Corrigendum ISO 80601-2-12:2011/Cor 1:2011. The main changes compared to the previous edition are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-2:2014 and IEC 60601-1-6:2010+AMD1:2013.

— determination of probability of component failure during the *expected service life*;

— delivered gas maximum enthalpy requirement;

— new test protocol for *internal electrical power source* operation time;

— performance test and disclosure requirements for other *inflation-types*;

— additional protections against hazardous outputs;

— clarification of performance requirements during abnormals testing;

— consideration of input gas of Oxygen 93 %; and

— harmonization of terminology with ISO 19223, where appropriate.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In this document, the following print types are used:

— Requirements and definitions: roman type;

— *Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

— “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this document,

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test),

— "can" is used to describe a possibility or capability, and

— "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012.

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment:*

— intended for use in an environment that provides specialized care for *patients* whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a *professional healthcare facility;*

NOTE 1 For the purposes of this document, such an environment is referred to as a critical care environment. *Ventilators* for this environment are considered life-sustaining.

NOTE 2 For the purposes of this document, such a *ventilator* can provide transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 3 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator.*

— intended to be operated by a *healthcare professional operator*; and

— intended for those *patients* who need differing levels of support from artificial ventilation including for *ventilator-dependent patients*.

A critical care *ventilator* is not considered to utilize a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the ventilation therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to a *ventilator breathing system*, or to a *ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

NOTE 4 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document is not applicable to *ME equipment* or an *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on artificial ventilation.

NOTE 6 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

This document is not applicable to *ME equipment* that is intended solely to augment the ventilation of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[2];

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84[3], the future replacement for ISO 10651-3[4];

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72:2015[5];

— *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79:2018[6] and ISO 80601-2-80:2018[7][1];

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[9];

— *continuous positive airway pressure* (*CPAP*) *ME equipment;*

— high-frequency jet ventilators (HFJVs) and high-frequency oscillatory ventilators (HFOVs), which are given in ISO 80601-2-87[63];

NOTE 7 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes.*

— oxygen therapy constant flow *ME equipment*; and

— cuirass or "iron-lung" ventilation equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator* and its *accessories*.

[1] ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

Accessories are included because the combination of the *ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 as indicated in Annex DD.

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3[12], IEC 60601-1-9[13], IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this document.

“Addition” means that the text of this document is additional to the requirements of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3[12], etc.

The term “this document” is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of the general standard applies, except as follows:

Replacement:

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60601-2-2:2017, *Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7010:2019, ISO 7396-1:2016, ISO 8836:2014, ISO 9000:2015, ISO 9360-1:2000, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-10:2007, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 60601-2-2:2017, IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-74:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE An alphabetized index of defined terms is found Annex EE.

201.3.201
emergency intake port
dedicated *gas intake port* through which ambient air is drawn when the supply of *fresh gas* is insufficient or absent

[SOURCE: ISO 4135:2001[14], 3.2.3, modified — Removed "air" from term, replaced ‘may be’ with ‘is’, added ‘*gas*’ and ‘or absent’ and deleted ‘and/or inflating gas’.]

201.3.202
flow-direction-sensitive component
component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:2001[14], 3.1.7, modified — Added ‘or *accessory*’ and replaced ‘must’ with ‘has to’.]

201.3.203
fresh gas
respirable gas delivered to a *ventilator breathing system*

[SOURCE: ISO 4135:2001[14], 3.1.8, modified — Added ‘*ventilator*’ and note to entry.]

Note 1 to entry: *Fresh gas* does not include the following:

— air drawn through the *emergency intake port*;

— air drawn through leaks in the *ventilator breathing system*;

— gas exhaled by the *patient*.

201.3.204
gas intake port
port through which gas is drawn for use by the *patient*

[SOURCE: ISO 4135:2001[14], 3.2.11, modified — Added "gas" to term, replaced ‘a ventilator or by a patient’ with ‘for use by the *patient*’.]

201.3.205
healthcare professional
appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services to families or communities

Note 1 to entry: This term functions as an adjective.

201.3.206
high-pressure input port
input port to which gas is supplied at a pressure exceeding 100 kPa

[SOURCE: ISO 4135:2001[14], 3.2.10.1, modified — Replaced ‘may be’ with ‘is’.]

201.3.207
minimum limited pressure
P_{LIM} min
lowest *airway pressure* during *normal use* or under *single fault condition*

Note 1 to entry: The *minimum limited pressure* can be subatmospheric.

201.3.208
monitoring equipment
ME equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*

201.3.209
**** professional healthcare facility***
facility that is continually staffed by suitably trained *healthcare professional operators*

EXAMPLE Hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services

201.3.210
protection device
part or function of *ME equipment* that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

201.3.211
ventilator-dependent
<*patient*> dependent upon artificial ventilation in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood. For the purposes of this document, dependent means the loss of therapy can require immediate medical intervention.

EXAMPLE *Patients* with Duchenne muscular dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 *Essential performance*

Addition:

201.4.3.101 * Additional requirements for *essential performance*

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

In the *risk management file*, the *manufacturer* shall:

aa) state the probability of component failure that results in the *ventilator* needing to be taken out of service during the *expected service life* assuming that the preventative inspection, maintenance and calibration are performed according to the *accompanying documents*; and

bb) summarize the methodology used to determine this probability.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of ventilation at the *patient-connection port* within the *alarm limits* set by the *operator*	a
or generation of an *alarm condition*	
oxygen level	201.12.4.101
airway pressure	201.12.4.106
CO_2 level, if provided	201.12.4.104
disconnection	201.12.4.109
expired volume, if provided	201.12.4.103
internal electrical power source nears depletion	201.11.8.101
gas supply failure	201.13.2.102
obstruction	201.12.4.108
PEEP	201.12.4.107

[a] Subclause 202.8.1.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document.

201.4.6 * *ME equipment* or *ME system* parts that contact the *patient*

Amendment (add at end of subclause):

aa) The *VBS* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause.

Addition:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) A *ventilator* with a pressurized gas input shall:

   1) operate and meet the requirements of this document throughout its *rated* range of input pressure; and

   2) not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.

b) A *ventilator* with a maximum *rated* input pressure in excess of 600 kPa shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

NOTE 1 Internal pressure regulators can be required to accommodate the *single fault condition* of maximum input pressure as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *VBS*. Under this condition, the flowrate from the *ventilator* is likely to be outside of its specification.

Check conformity by functional testing in normal use and under normal condition with the most adverse operating settings, by functional testing in single fault condition and inspection of the risk management file.

201.4.11.101.2 Compatibility requirement

If the *ventilator* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016 then:

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016; and

b) under *normal condition*,

   1) the maximum input flowrate required by the *ventilator* for each gas shall not exceed 60 l/min averaged over 10 s at a pressure of 280 kPa, measured at the *gas intake port*; and

   2) any transient input flowrate shall not exceed 200 l/min averaged over 3 s,

   or:

   3) the *accompanying documents* shall disclose:

      i) the maximum input flowrate required by the *ventilator* for each gas at a pressure of 280 kPa averaged over 10 s, measured at the *gas intake port*;

      ii) the maximum transient input flowrate averaged for 3 s required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*; and

iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the *risk* that the ventilator interferes with the operation of adjacent equipment.

Check conformity by functional testing in normal use and under normal condition with the most adverse operating settings and by inspection of the accompanying documents.

EXAMPLE Highest driving gas consumption under worst-case settings for *set rate* and *tidal volume* and worst-case *medical gas pipeline system* conditions within the *rated* range for inlet pressure.

201.5 General requirements for testing of *ME equipment*

Clause 5 of the general standard applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of *ME equipment*

201.5.101.1 *Ventilator* test conditions

a) For testing, the *ventilator*

1) shall be connected to gas supplies as specified for *normal use*,

2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

201.5.101.2 * Gas flowrate and leakage specifications

All requirements for gas flowrate, volume and leakage in this document,

a) are expressed at *STPD*,

b) except for those associated with the *VBS*, which are expressed at *BTPS*.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 * *Ventilator* testing errors

a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.

b) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the technical description.

Check conformity by inspection of the instructions for use and the technical description.

201.6 Classification of *ME equipment* and *ME systems*

Clause 6 of the general standard applies.

201.7 *ME equipment* identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.3 * Consult *accompanying documents*

Replacement:

The *ventilator* shall be marked with the *safety sign* for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005/COR1:2006, Table D.2, Number 10).

Addition:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

  1) fulfil the requirements of 201.102.1; and

  2) be marked with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable. See also 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101.

b) If marking the *accessory* is not practicable, this information may be placed in the instructions for use.

Check conformity by inspection, inspection of the risk management file for any limitations or adverse effects of the accessory, and where necessary, inspection of the instructions for use.

201.7.2.13.101 Additional requirements for physiological effects

a) All natural rubber latex-containing components in the *gas pathways* or *accessories* shall be marked as containing latex.

b) Such marking shall be *clearly legible*.

c) Symbol 5.4.5 from ISO 15223-1:2016, (Table 201.D.2.101, symbol 10) may be used.

d) The instructions for use shall disclose all natural rubber latex-containing components.

Check conformity by inspection.

201.7.2.17.101 Additional requirements for protective packaging

a) Packages containing breathing attachments intended for single use or for reuse shall have *clearly legible* markings of the following

  1) a description of the contents.

2) an identification reference to the batch, type or serial number or symbols 5.1.5 (Table 201.D.2.101, symbol 7), 5.1.6 (Table 201.D.2.101, symbol 8) or 5.1.7 (Table 201.D.2.101, symbol 9) from ISO 15223-1:2016.

3) the word “LATEX”, or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.2.101, symbol 10), if containing natural rubber latex.

b) For a specific *model or type reference*, the indication of single use shall be consistent for the *model or type reference*.

Check conformity by inspection.

201.7.2.18 External gas source

Amendment (add before the first dash):

aa) the gas name or chemical symbol in accordance with ISO 5359:2014;

bb) the *rated* range of gas pressure;

cc) for oxygen gas inputs, the *rated* range of oxygen concentration;

dd) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used.

EXAMPLE Colour coding to match the colour of the flexible hose or a gas cylinder intended to be attached to the inlet connector.

NOTE In some countries, other colour coding is used.

Addition:

201.7.2.101 * Additional requirements for marking on the outside of *ME equipment* or *ME equipment* parts

a) The *ME equipment*, parts or *accessories* shall have *clearly legible* markings including

1) any special storage, handling or operating instructions.

2) any warnings or precautions relevant to the immediate operation of the *ventilator*.

3) an arrow indicating the intended direction of gas flow:

i) for the *gas output port;* and

ii) for the *gas return port*.

4) Symbol 0794 of ISO 7000 (Table 201.D.2.101, symbol 11) or Symbol 0795 of ISO 7000 (Table 201.D.2.101, symbol 12) may be used.

b) If applicable, *operator*-accessible *ME equipment*, parts or *accessories* shall have *clearly legible* markings of the following

1) for a *ventilator* intended to be used in the magnetic resonance (MR) environment,

i) Symbol 7.3.1-1 (Table 201.D.2.101, symbol 14) or Symbol 7.3.1-2 (Table 201.D.2.101, symbol 15) of IEC 62570 for an ‘MR Safe’ *ventilator*, or

ii) Symbol 7.3.2 of IEC 62570 (Table 201.D.2.101, symbol 16) for an 'MR Conditional' *ventilator*, in accordance with IEC 62570:2014.

2) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*.

3) an indication of the date after which *ME equipment*, part or *accessory* should not be used, expressed as the year and month.

i) Symbol 5.1.4 of ISO 15223-1:2016 (Table 201.D.2.101, symbol 1) may be used.

4) a warning not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas intake – Do not obstruct

i) A symbol evaluated according to IEC 62366-1 as information for safety may be utilized.

Check conformity by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flowrate and leakage specifications:

aa) shall be expressed at *STPD*; except

bb) for those associated with the *VBS* which shall be expressed at *BTPS*.

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

— Name or trade name and address of

  — the *manufacturer*, and

  — where the *manufacturer* does not have an address within the locale, an authorized representative within the locale,

  to which the *responsible organization* can refer;

Addition:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose the following:

a) if the *ventilator*, its parts or *accessories* are intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *ventilator*, its parts or *accessories* would be reused; and

b) the intended range of *tidal volume*.

Check conformity by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include:

a) * a warning statement to the effect of "Warning: Do not cover the ventilator or place in a position that affects proper operation", including applicable examples.

EXAMPLE 1 **WARNING**: Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat, thereby interfering with patient ventilation.

EXAMPLE 2 **WARNING**: Do not block the gas intake port or emergency intake port, thereby interfering with patient ventilation.

b) * a warning statement to the effect of "Warning: Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health."

EXAMPLE 3 **WARNING**: Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4:2002[15]) with mask can result in patient death if the ventilator fails.

c) * a warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health."

If applicable, the instructions for use shall include the following:

d) * a warning statement to the effect of "Warning: The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."

e) * a warning statement to the effect of "Warning: The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."

f) * a warning statement to the effect of "Warning: The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health."

g) * a warning statement to the effect of "Warning: The ventilator accuracy can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebuliser.

h) * a warning statement to the effect of "Warning: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the *rated* range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health."

i) * a warning statement to the effect of "Warning: When using nebulisation or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.

Check conformity by inspection.

201.7.9.2.8.101 * Additional requirements for start-up *procedure*

NOTE A start-up *procedure* includes a pre-use functional test that is used to determine whether the *ventilator* is ready for use.

a) The instructions for use shall disclose a method by which the following can be functionally tested by the *healthcare professional operator* to determine if they are operating correctly:

1) the assembled *VBS*;

2) switchover to and operation from the *internal electrical power source*; and

3) all of the *alarm signals*, including the *alarm signals* from any *distributed alarm systems.*

b) Portions of this test method may:

1) be automatically performed by the *ventilator;* or

2) require *healthcare professional operator* action.

EXAMPLE Combination of the power-on self-test routines and *healthcare professional operator* action.

Check conformity by inspection of the instructions for use.

201.7.9.2.9.101 * Additional requirements for operating instructions

The instructions for use shall disclose

a) a listing of the following pressures:

1) *maximum limited pressure* ($P_{LIM\,\max}$);

2) if provided, the *rated* range to which the *maximum working pressure* ($P_{W\max}$) can be set, if adjustable;

3) the means by which the *maximum working pressure* is accomplished;

EXAMPLE 1 Pressure cycling, pressure limiting, pressure generation.

4) a statement that *airway pressure* can be subatmospheric during the *expiratory phase* for a *ventilator* that can generate subatmospheric pressure in the *expiratory phase*, if applicable;

5) the *minimum limited pressure* at the *patient-connection port*, for *ventilators* that can generate subatmospheric pressure in the *expiratory phase*.

b) * the *rated* range of the following characteristics of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:

1) inspiratory *gas pathway* resistance,

2) expiratory *gas pathway* resistance, and

3) *VBS* compliance.

i) These specifications may be presented in ranges.

ii) The accuracies of set and monitored volumes may be presented as a function of these characteristics.

NOTE Compliance and resistance can be non-linear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min and the maximum flowrate or the maximum pressure).

c) the conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use.

EXAMPLE 2 Acceptable range of water level in a *humidifier*.

EXAMPLE 3 Interval of calibration of a flow sensor.

d) an explanation of the meaning of the IP classification marked on the *ME equipment*.

e) an indication as to whether the *ventilator* is intended for non-invasive ventilation.

EXAMPLE 4 This ventilator is intended for use with mask ventilation.

f) any special storage, handling or operating instructions.

g) a cross reference between the *manufacturer*-specific naming of the *ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.

Check conformity by inspection.

201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization*

Amendment: (add after normal use)

or in *single fault condition*

Amendment: (add after bulleted list)

aa) The instructions for use shall identify which portions of the *gas pathways* through the *ventilator* can become contaminated with body fluids or by contaminates carried by expired breathing gases during both *normal condition* and *single fault condition*.

Addition:

201.7.9.2.14.101 * Additional requirements for *accessories*, supplementary equipment, used material

a) The instructions for use of the *ventilator* shall include a statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the *ventilator breathing system*.

b) If applicable, the instructions for use of the *ventilator* shall disclose:

1) any restrictions on the positioning of components within the *ventilator breathing system*; and

EXAMPLE Where such components are *flow-direction-sensitive components*.

2) any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *ventilator* (additional requirements are found in 201.16).

Check conformity by inspection and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.2.16.101 * Additional requirements for reference to the technical description

Where the technical description is supplied as a separate document from the instructions for use, then the instructions for use shall:

a) list the contents of the technical description; and

b) wherever appropriate, provide a cross reference to the additional information available in the technical description.

Check conformity by inspection.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose:

a) * a summary description of the filtering or smoothing techniques for measured or computed variables that are displayed or used for control necessary for the *operator* to form a mental model of the operation of the *ventilator*;

b) a pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the instructions for use; and

c) a summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*.

If applicable, the technical description shall disclose

d) the essential technical characteristics of each recommended *breathing system filter*.

EXAMPLE Dead space and resistance.

Check conformity by inspection.

201.7.9.3.101 Additional requirements for the technical description

The technical description shall disclose:

a) a description of a *procedure* for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during start-up; and

b) which checks are performed automatically.

Check conformity by inspection of the technical description.

201.8 Protection against electrical *hazards* from *ME equipment*

Clause 8 of the general standard applies.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

Clause 9 of the general standard applies, except as follows:

Addition:

201.9.6.2.1.101 * Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *ventilator* shall be:

   1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and

   2) disclosed in the instructions for use.

b) The A-weighted sound power level shall be:

   1) calculated according to 8.2.5 and 8.6 of ISO 3744:2010; and

   2) disclosed in the instructions for use.

Check conformity with the following test:

c) *Place the ventilator on the sound-reflecting plane and attach the least favourable VBS from those indicated in the instructions for use.*

   NOTE 1 The least favourable VBS configuration can vary by ventilation-mode, inflation-type and flow pattern, as applicable.

d) *If a humidifier is provided with the ventilator, include the humidifier filled to the least favourable level in the test.*

e) *Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.*

   — *Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the ventilator.*

   — *Connect the patient-connection port to the test lung.*

f) *Set the ventilator to the least favourable ventilation-mode, inflation-type and flow pattern, as applicable, that generates ventilation as indicated in Table 201.102.*

   NOTE 2 The least favourable ventilation-mode, inflation-type and flow pattern can vary by VBS configuration.

g) *Using a microphone of the sound level meter, conforming with the requirements of type 1 instruments specified in* IEC 61672-1:2013, *measure the maximum time-weighted sound*

pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}) at 10 positions in a hemisphere with a radius from the geometric centre of the ventilator in a free field over a reflecting plane as specified in 8.1.1 of ISO 3744:2010. Average the values in conformance with 8.2.2 of ISO 3744:2010.

*** Table 201.102 — Test conditions for acoustic tests**

Adjustable parameter	Test condition		
	For a *ventilator* intended to provide *tidal volume*		
	$V_{tidal} \geq 300$ ml	300 ml $\geq V_{tidal} \geq 50$ ml	$V_{tidal} \leq 50$ ml
Tidal volume, V_{tidal}[a]	500 ml	150 ml	30 ml
Set rate	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1:2	1:2	1:2
BAP	10 hPa (10 cmH$_2$O)	10 hPa (10 cmH$_2$O)	10 hPa (10 cmH$_2$O)
Linear resistance, R[b][17][18][19]	5 hPa(l/s)$^{-1}$ ±10 %	20 hPa(l/s)$^{-1}$ ±10 %	50 hPa(l/s)$^{-1}$ ±10 %
Isothermal Compliance, C[b]	50 ml hPa^{-1} ±10 %	20 ml hPa^{-1} ±10 %	1 ml hPa^{-1} ±10 %

[a] V_{tidal} is measured by means of a pressure sensor at the test lung, where $V_t = C \times (P_{max})$, and

V_t is the volume delivered to the test lung

C is the isothermal compliance of the test lung

P_{max} is the maximum pressure measured in the test lung

[b] The accuracy for C and R applies over the ranges of the measured parameters.

h) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.*

i) *Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.*

j) *Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.*

k) *Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.*

201.9.101 * Additional requirements for suction *procedures*

a) The instructions for use shall disclose recommended ventilation settings for use with a closed *suction catheter*.

b) A *ventilator* shall continue to function as intended after the use of a closed *suction catheter*:

  1) for each *ventilation-mode* with the lowest *tidal volume* of each intended *tidal volume* range indicated in the instructions for use; and

  2) using the *VBS* configuration with the lowest compliance of those indicated in the instructions for use.

NOTE 1 For the purposes of this requirement, *pressure-control* based ventilation with a volume target is considered a form of *volume-control*.

Check conformity by inspection of the instructions for use and with the following test:

c) *Connect a suction system, as shown in Figure 201.101, leaving the patient-connection port of the closed suction catheter adaptor open to air and the ventilator disconnected. Utilize a closed suction catheter of minimum inside diameter of 2,95 mm (French (Charriere) equivalent size 14 F).*

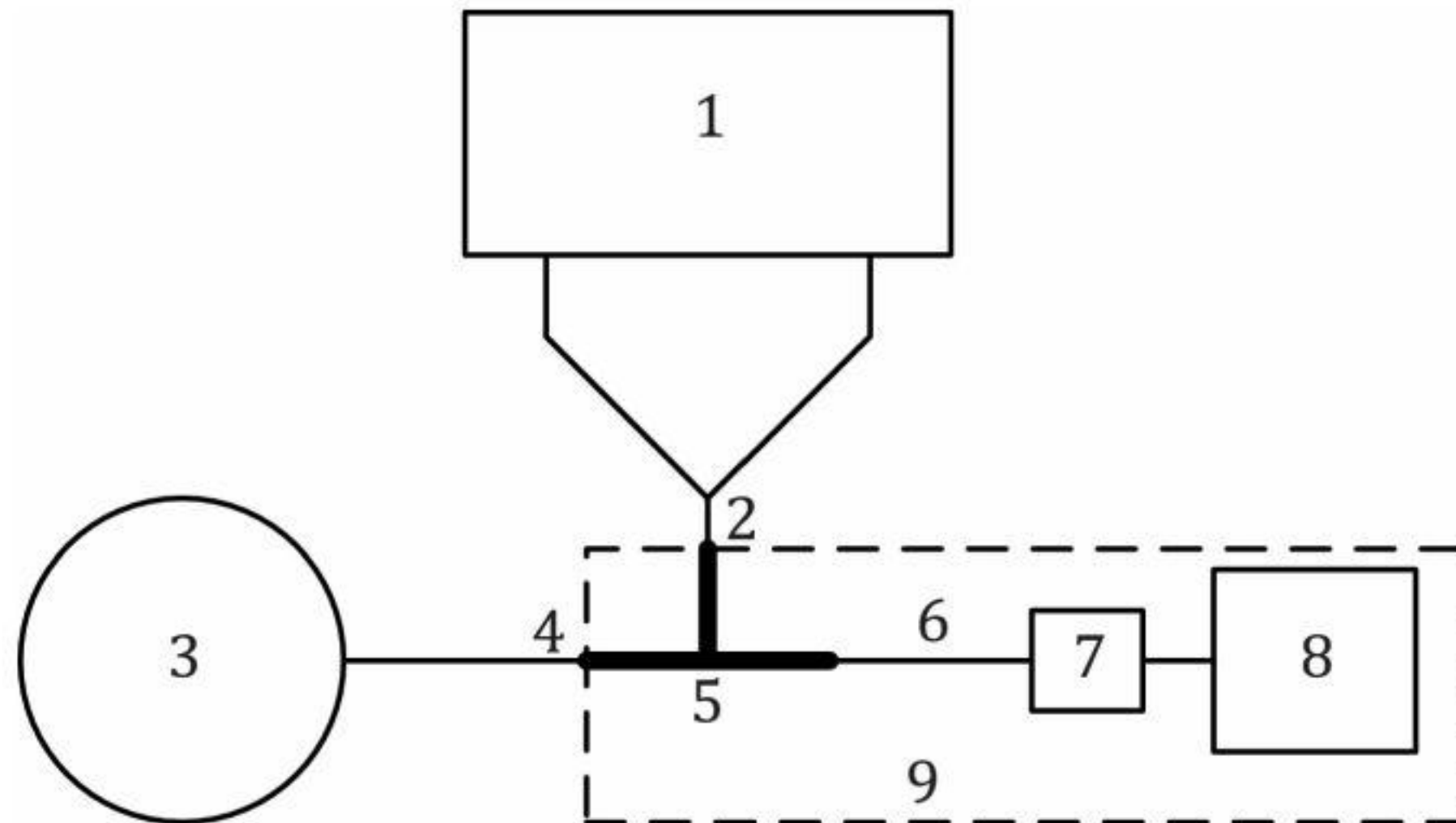
Key

1 *ventilator* under test
2 *patient-connection port* of *VBS* before adding the closed *suction catheter* adaptor
3 test lung
4 *patient-connection port* of *VBS* after adding the closed *suction catheter* adaptor
5 closed *suction catheter* adaptor
6 14 Fr closed *suction catheter* conforming with ISO 8836:2014
7 flow control valve (can be incorporated in 8)
8 suction equipment conforming with ISO 10079-1:2015[20] or ISO 10079-3:2014[21]
9 suction system

Figure 201.101 — Typical closed suctioning test setup

d) *Adjust the suction equipment as follows:*

— *Close the flow control valve and adjust the vacuum regulator of the suction equipment to an occluded vacuum of 200 hPa (204 cmH_2O) below ambient atmospheric pressure.*

— *Open and set the flow control valve to give a free air flow (suction flow) of:*

i) *30 l/min, for a ventilator intended to provide tidal volume, $V_{tidal} \geq 300$ ml;*

ii) *15 l/min, for a ventilator intended to provide tidal volume, 300 ml $\geq V_{tidal} \geq 50$ ml; and*

iii) *5 l/min, for a ventilator intended to provide tidal volume, $V_{tidal} \leq 50$ ml.*

e) *Disable the suction flow without affecting the flow control valve setting.*

f) *Connect the ventilator as shown in Figure 201.101 utilizing the lowest compliance VBS indicated in the instructions for use for the intended tidal volume range.*

g) *Connect a test lung to the patient-connection port of the closed suction catheter adaptor. Utilize a test lung with compliance:*

— *10 ml/hPa ± 10 %, for a ventilator intended to provide tidal volume, $V_{tidal} \geq 300$ ml;*

— *3 ml/hPa ± 10 %, for a ventilator intended to provide tidal volume, 300 ml ≥ V_{tidal} ≥ 50 ml; and*

— *0,5 ml/hPa ± 10 %, for a ventilator intended to provide tidal volume, V_{tidal} ≤ 50 ml.*

h) *Do not enable any special suction procedure ventilator operational mode and retract the closed suction catheter.*

i) *Perform any compliance correction as indicated in the instructions for use.*

j) *Select a volume-control inflation-type with the following settings:*

— *minimum tidal volume for the intended tidal volume range;*

— *set rate: 10 min^{-1}; and*

— *trigger: off or, if not so equipped, at the most insensitive method and setting.*

k) *Wait until stability is achieved.*

l) *Advance the closed suction catheter between 1 cm and 2 cm beyond the patient-connection port.*

m) *Enable the suction flow, without affecting the flow control valve setting, and maintain for 30 s.*

NOTE 2 Some *alarm conditions* might become active. This is an expected possibility.

n) *Terminate the suction flow by closing the suction equipment valve and retract the suction catheter.*

NOTE 3 Retracting the *suction catheter* into its supplied sleeve can be important to seal the *gas pathway* and reduce gas leakage.

o) *Wait until stability is achieved.*

p) *Confirm that the ventilator continues to function as intended.*

EXAMPLE The *tidal volume* is within specification.

q) *Repeat c) to p) for each intended tidal volume range.*

r) *Repeat c) to q) using a pressure-control inflation-type with the following parameters in lieu of d):*

— *ventilation pressure of 5 cmH_2O or, if the ventilator cannot be set that low, the lowest setting;*

— *set rate: 10 min^{-1}; and*

— *trigger: off or, if not so equipped, at the most insensitive setting.*

s) *Repeat c) to q) using the recommended ventilation-mode and settings for use with a closed suction catheter in lieu of d) unless the recommended ventilation-mode and settings have already been tested.*

201.10 Protection against unwanted and excessive radiation *hazards*

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other *hazards*

Clause 11 of the general standard applies, except as follows:

201.11.1.2.2 * *Applied parts* not intended to supply heat to a *patient*

Amendment (add between the existing paragraphs):

Over the *rated* flowrate range and at the maximum *rated* operating temperature, the temperature of the gas delivered by the *ventilator* at the *patient-connection port,* both with and without each *humidifier* specified for use in the instructions for use, when averaged over 120 s shall neither exceed:

aa) 70 °C; nor

bb) an energy equivalent to 43 °C and 100 % relative humidity (specific enthalpy not to exceed 197 kJ/m³ dry air).

Table 201.103 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.103 — Examples of permissible combinations of temperature and relative humidity

Temperature °C	Relative humidity %
43	100
44	95
45	90
48	76
50	69
55	52
60	40
65	30
70	23

Addition:

201.11.6.5.101 * Additional requirements for ingress of water or particulate matter into *ME equipment* or *ME system*

a) *Enclosures* of *ventilators* shall provide at least an IP21 degree of protection to the harmful ingress of water.

b) *Enclosures* of *ventilators* should provide an IP22 degree of protection to the harmful ingress of water.

Check conformity by the tests of IEC 60529:1989+AMD1:1999+AMD2:2013 with the ventilator placed in the least favourable position of normal use and by inspection. After these procedures, confirm that basic safety and essential performance are maintained.

201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (add additional requirement as new first paragraph):

aa) *Gas pathways* through the *ventilator* and its *accessories* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

1) for *cleaning* and *disinfection*; or

2) *cleaning* and *sterilization*.

NOTE 1 Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012.

Amendment (add additional requirement and replace the conformance test):

bb) *Ventilator enclosures* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of cross infection of the next *patient*.

NOTE 2 ISO 14159:2002[22] provides guidance for the design of *enclosures*.

cc) *Processing* instructions for the *ventilator* and its *accessories* shall:

1) conform with ISO 17664:2017 and ISO 14937:2009; and

2) be disclosed in the instructions for use.

Check conformity by inspection of the risk management file. When conformity with this document could be affected by the cleaning or the disinfection of the ventilator or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these procedures, ensure that basic safety and essential performance are maintained. Confirm that the manufacturer has evaluated the effects of multiple process cycles and the effectiveness of those cycles.

201.11.6.7 *Sterilization* of *ME equipment* or *ME system*

Amendment (add note before conformance test):

NOTE Additional requirements are found in 11.6.6 of IEC 60601-1:2005+AMD1:2012.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the conformance statement):

aa) The *manufacturer* of a *ventilator, VBS*, its parts or *accessories* shall address in the *risk management process* the *risks* associated with the leaching or leaking of substances into the *gas pathway*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

cc) A *VBS*, its parts or *accessories* that contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, in a concentration that is above 0,1 % weight by weight of any article, shall be marked as containing such substances:

1) on the *VBS*, its parts or *accessories* itself; or

2) on the packaging.

3) The symbol of:

i) EN 15986:2011[25] (Table 201.D.2.101, symbol 13) may be used for phthalates.

ii) ISO 7000-2725 (Table 201.D.2.101, symbol 9) may be used for other substances.

4) If the *intended use* of a *VBS*, its parts or *accessories* includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these substances shall be included in the *risk management file*.

5) The instructions for use shall contain information:

i) on *residual risks* for these *patient* groups; and

ii) if applicable, on appropriate precautionary measures.

Addition:

201.11.8.101 * Additional requirements for interruption of the power supply/*supply mains* to *ME equipment*

The *ventilator* shall be equipped with

a) an *internal electrical power source* capable of powering the *ventilator* for at least 30 min when the *supply mains* falls outside the values necessary to maintain normal operation.

b) a means of determining the remaining capacity or operation time provided by the *internal electrical power source*.

1) This indication may be qualitative.

c) a means to determine the power source that is currently powering the *ventilator*.

A *ventilator* shall

d) be equipped with an *alarm system* that detects a *technical alarm condition* or

1) the *alarm condition* for switchover to an *internal electrical power source* shall be at least a *low priority*.

e) generate an *information signal* to indicate a switchover to an *internal electrical power source*.

f) be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when the *internal electrical power source* nears depletion, at least 10 min prior to the loss of ventilation.

   1) The *internal electrical power source* nears depletion *alarm condition* shall be at least a *medium priority.*

   2) As the *internal electrical power source* depletes further, at least 5 min prior to the loss of ventilation, the depletion *internal electrical power source technical alarm condition* shall escalate to *high priority*.

The instructions for use shall disclose

g) for each intended *tidal volume* under the conditions of Table 201.102, the operational time of the *ventilator* when powered from

   1) an aged (see k), fully charged *internal electrical power source* and

   2) an external reserve electrical power source, if provided.

   NOTE For the purposes of this document, an external reserve electrical power source is part of an *ME system* providing electrical power external to the *ventilator*.

h) the means by which the secondary *supply mains*, if provided, can be tested.

i) the behaviour of the *ventilator* after a switchover:

   1) to the *internal electrical power source;* or

   2) to the external reserve electrical power source, if provided.

   EXAMPLE 1 Describing which *accessories* or integrated components such as a heated exhalation manifold or a heated *humidifier* no longer remain functional after a switchover to the *internal electrical power source* or a secondary *supply mains,* if provided.

   EXAMPLE 2 Describing any limitations to the ventilation function after switchover.

j) the behaviour of the *ventilator* while:

   1) the *internal electrical power source* is recharging; and

   2) the external reserve electrical power source is recharging, if provided.

Check conformity by inspection of the instructions for use, functional testing and the following test.

k) Age a new internal electrical power source by operating the ventilator from the internal electrical power source using the worst-case intended tidal volume and inflation-type under the conditions of Table 201.102:

   1) until the high priority internal electrical power source nears depletion technical alarm condition becomes active;

   2) recharge the internal electrical power source by connecting the ventilator to supply mains;

   *3) * repeat 1) and 2) 10 times; and*

4) ** for a transit-operable ventilator, repeat 1) and 2) an additional 40 times.*

5) *Instead of using the ventilator, discharging and charging circuits may be used with an equivalent profile simulating worst-case conditions:*

   i) over the discharging time; and

   ii) over the charging time.

l) *Operate the ventilator using an intended tidal volume and inflation-type under the conditions of Table 201.102.*

m) *Confirm that the medium priority alarm condition occurs at least 10 min prior to the loss of ventilation.*

n) *Confirm that the high priority alarm condition occurs at least 5 min prior to the loss of ventilation.*

o) *Repeat l) to n) for each remaining range of intended tidal volume.*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The controls of a *ventilator* shall be *clearly legible* under the conditions specified in 7.1.2 of IEC 60601-1:2005+AMD1:2012.

Check conformity by application of the tests in 7.1.2 of IEC 60601-1:2005+AMD1:2012.

Addition:

201.12.1.101 * *Volume-control inflation-type*

a) With a *volume-control inflation-type* selected and the *ventilator* operating in *normal condition*, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

   EXAMPLE ±(5 +(10 % of the set volume)) ml

b) This disclosure shall include at least:

   1) the maximum error of the *inspiratory volume* in relation to the set *tidal volume*;

   2) the maximum error of the *PEEP* in relation to the set value of *BAP*; and

3) * the maximum error of the inspiratory oxygen (O_2) concentration at the *patient-connection port* in relation to the set value.

4) the disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

c) All of the errors may be reported separately for the following ranges of intended *tidal volume*:

1) $V_{tidal} \geq 300$ ml;

2) 300 ml $\geq V_{tidal} \geq 50$ ml; and

3) $V_{tidal} \leq 50$ ml

d) The accuracy of the performance of the *ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configurations indicated in the instructions for use.

NOTE 1 The worst-case *VBS* configuration can be different for each error or *nominal tidal volume*.

NOTE 2 In determining the worst-case configuration, consider use with active and passive humidification.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformity by inspection of the risk management file for the rationale, if applicable, and with the following tests:

NOTE 3 In some cases, the following tests can be carried out simultaneously.

f) Tidal volume and end-expiratory pressure errors

1) Set up the ventilator as shown in Figure 201.102.

2) If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a humidifier is used, fill the humidifier to the maximum water level prior to determining the VBS compliance.

3) Utilize the test parameters and settings of the first applicable row (selected by intended tidal volume) of Table 201.104.

4) Wait for steady-state conditions to be achieved.

5) Determine the tidal volume, for example via integration of the flow signal provided by a calibrated flow sensor located at the patient-connection port or by the product of the test lung compliance and the measured change of lung pressure, compensated for temperature effects due to fast compression of the gas, if necessary.

NOTE 4 Additional information on the construction of an isothermal test lung is found in Reference [23].

Key

1 *ventilator* under test

2 pressure sensor

3 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms

4 oxygen sensor

5 data acquisition system, with minimum sample rate of 200 samples/s

6 temperature sensor

7 test lung resistance (R_{lung})

8 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms

9 test lung compliance (C_{lung})

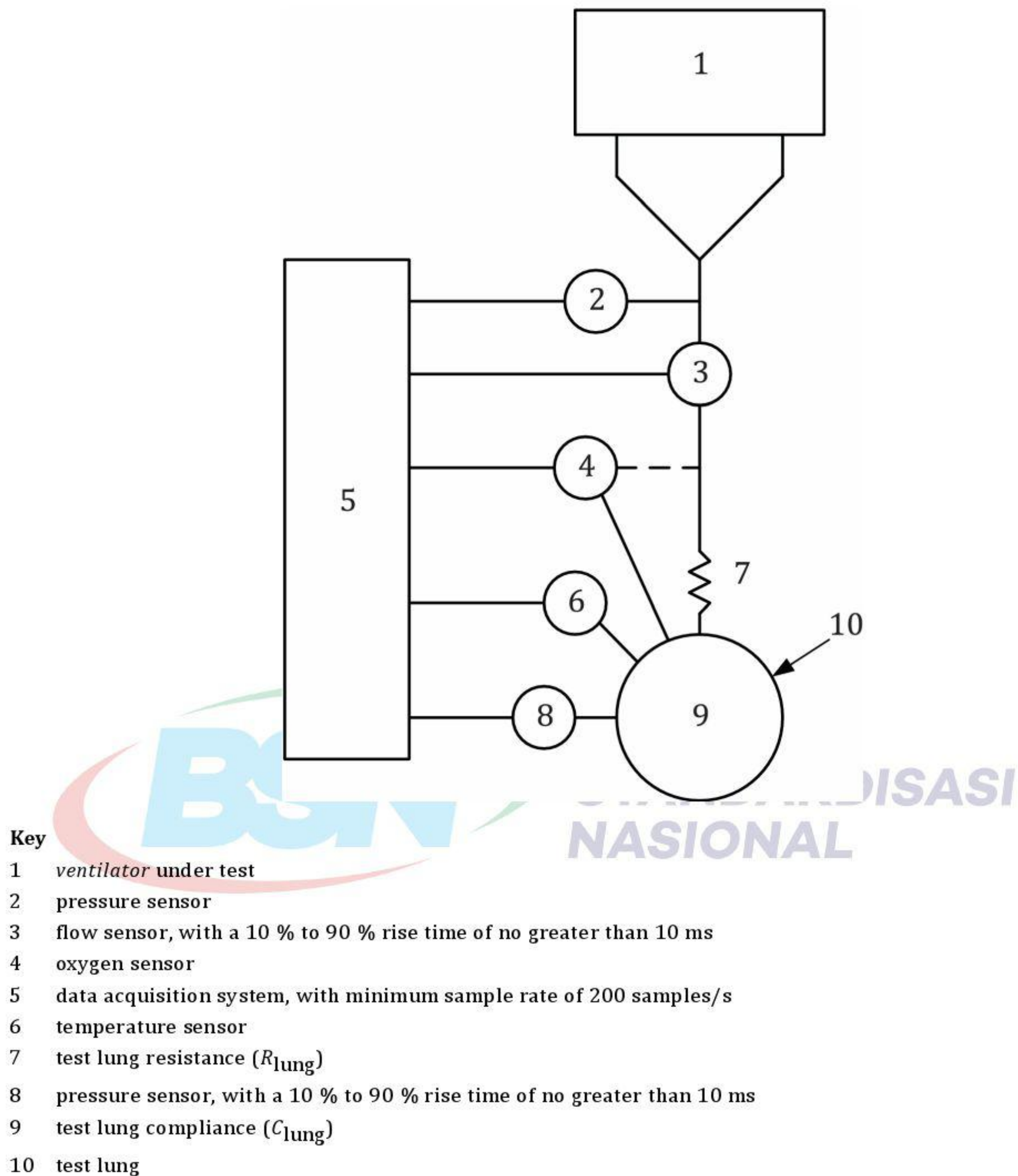
10 test lung

The oxygen sensor may be placed in the *VBS*.

Figure 201.102 — Typical test setup for *volume*- and *pressure-control inflation-type* accuracy

6) *Compare the result with the acceptance criteria derived from the volume setting for the test, the measurement uncertainty and the tolerance indicated in the instructions for use.*

7) *If the ventilator is equipped with tidal volume monitoring equipment, determine the accuracy of the tidal volume monitoring equipment by comparing its reading adjusted for the measurement uncertainty to the tidal volume determined in 5). Refer to Table 201.104.*

8) *Determine the PEEP as the average of the airway pressure measurements over the last 50 ms of the expiratory phase.*

Table 201.104 — *Volume-control inflation-type* testing

Test number	Test lung parameters		*Ventilator* settings				
	Compliance ml/hPa ±10 %	Linear resistance[17][18][19] hPa/l/s ±10 %	*Tidal volume* ml	*Set rate*[a] breaths/min	*Inspiratory time* s	O_2 %	*BAP* hPa (cmH_2O)
1	50	5	500	20	1	30	5
2	50	20	500	12	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	12	1	90	10
7	10	50	300	20	1	30	10
8	10	10	200	20	1	90	5
9	3	10	50	30	0,6	30	5
10	3	20	50	30	0,6	30	10
11	3	50	50	20	0,6	60	5
12	3	20	30	30	0,6	30	5
13	3	50	30	20	0,6	90	10
14	1	20	30	30	0,6	90	5
15	1	100	30	30	0,6	30	10
16	1	200	20	50	0,4	30	5
17	1	200	15	50	0,4	60	10
18	1	50	10	60	0,4	60	5
19	0,5	50	5	60	0,4	60	10
20	0,5	200	5	30	0,4	30	5
21	0,5	200	5	60	0,4	30	10

[a] If the *end-expiratory flow* does not reach zero, reduce the *set rate* until it does.

9) *Compare the result with the acceptance criteria derived from the BAP setting for the test, the measurement uncertainty and the resulting difference with the tolerance indicated in the instructions for use.*

10) *Repeat 3) to 9) for 30 consecutive inflations.*

11) *Repeat 4) to 10) for each applicable row (selected by intended tidal volume) of Table 201.104.*

12) *If a humidifier is included in the VBS, repeat the tidal volume tests with the minimum humidifier water level without re-determining the VBS compliance.*

13) *Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat 2) to 12) for each flow pattern available on the ventilator.*

14) *If the ventilator permits operation without compliance correction, repeat 2) to 10) without compliance correction.*

g) *O_2 error*

The accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration measuring device at the patient-connection port or inside the test lung. If the sensor is located at the patient-connection port, the value of the concentration is the flow-weighted average concentration during the inflation phase.

1) *Evaluate the measured O_2 concentration with the acceptance criteria derived from the O_2 setting for the test and the measurement uncertainty. Compare the resulting difference with the tolerance indicated in the instructions for use. If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration. If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inflation phase.*

2) *If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.*

3) *Compare each result with the acceptance criteria derived from the O_2 setting for the test in f), above, the measurement uncertainty and the tolerance indicated in the instructions for use.*

201.12.1.102 * *Pressure-control inflation-type*

a) With a *pressure-control inflation-type* selected and the *ventilator* operating in *normal condition*, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ±(3,0 +(5 % of the set pressure)) hPa; (±(3,0 +(5 % of the set pressure)) cmH_2O)

b) This disclosure shall include at least:

1) the maximum error of the *airway pressure* (P_{aw}) at the end of the *inflation phase* in relation to the set value;

2) the maximum error of *PEEP* in relation to the set value *BAP*; and

3) * the maximum error of the inspiratory oxygen (O_2) concentration at the *patient-connection port* in relation to the set value.

4) the disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

c) All of the errors may be reported separately for the following ranges of intended *tidal volume*:

1) $V_{tidal} \geq 300$ ml;

2) 300 ml $\geq V_{tidal} \geq 50$ ml; and

3) $V_{tidal} \leq 50$ ml.

d) The accuracy of the performance of the *ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configuration indicated in the instructions for use.

NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.

In determining the worst-case configuration consider use with active and passive humidification.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformity by inspection of the risk management file for the rationale, if applicable, and with the following tests:

NOTE 2 In some cases, the following tests can be carried out simultaneously.

f) End-inspiratory and end-expiratory pressure errors

1) Set up the ventilator as shown in Figure 201.102.

2) If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a humidifier is used, fill the humidifier to the maximum water level prior to determining the VBS compliance.

3) Utilize the test parameters and settings of the first applicable row (selected by typical intended tidal volume) of Table 201.105. Wait until steady-state conditions are achieved.

4) Determine the airway pressure at the end of the inflation phase as the average over the preceding 50 ms.

5) Compare the result with the acceptance criteria derived from the pressure setting for the test, the measurement uncertainty and the resulting difference with the tolerance indicated in the instructions for use.

6) Determine the tidal volume, for example via integration of the flow signal provided by a calibrated flow sensor located at the patient-connection port, or by the product of the test lung compliance and the measured change of lung pressure, compensated for temperature effects due to fast compression of the gas, if necessary.

NOTE 3 Additional information on the construction of an isothermal test lung is found in Reference [23].

7) If the ventilator is equipped with tidal volume monitoring equipment, determine the accuracy of the tidal volume monitoring equipment by comparing its reading adjusted for the measurement uncertainty to the tidal volume determined in 6). Refer to Table 201.104.

8) Determine the PEEP as the average of the airway pressure measurements over the last 50 ms of the expiratory phase.

9) Compare the result with the acceptance criteria derived from the BAP setting for the test, the measurement uncertainty and the resulting difference with the tolerance indicated in the instructions for use.

10) Repeat 2) to 9) for 30 consecutive inflations.

11) Repeat 2) to 10) for each applicable row (selected by intended tidal volume) of Table 201.105.

12) If a humidifier is included in the VBS, repeat the airway pressure tests with the minimum humidifier water level without re-determining the VBS compliance.

13) If the ventilator permits operation without compliance correction, repeat 2) to 12) without compliance correction.

g) O_2 error

The accuracy of the inspiratory O_2 concentration of the gas delivered is assessed by placing the sensor of an O_2 concentration measuring device at the patient-connection port or inside the test lung. If the sensor is located at the patient-connection port, the value of the concentration is the flow-weighted average concentration as a function of flow during the inflation phase.

1) Evaluate the measured O_2 concentration with the acceptance criteria derived from the O_2 setting for the test, the measurement uncertainty. Compare the resulting difference with the tolerance indicated in the instructions for use. If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration. If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inflation phase.

If the O_2 concentration measuring device has pressure dependencies, compensate for these dependencies.

2) Compare each result with the acceptance criteria derived from the O_2 setting for the test in f), above, the measurement uncertainty and the tolerance indicated in the instructions for use.

Table 201.105 — *Pressure-control inflation-type* testing

Test number	Intended *tidal volume*[a]	Test lung parameters		*Ventilator* settings				
		Compliance	Linear Resistance [17][18][19]	*Set rate*[b]	*Inspiratory time*[c]	*Δ inspiratory pressure*[d]	O_2 %	*BAP*
	ml	ml/hPa ±10 %	hPa/l/s ±10 %	breaths/min	s	hPa		hPa (cmH_2O)
1	500	50	5	20	1	10	30	5
2	500	50	20	12	1	15	90	10
3	500	20	5	20	1	25	90	5
4	500	20	20	20	1	25	30	10
5	300	20	20	20	1	15	30	5
6	300	20	50	12	1	25	90	10
7	300	10	50	20	1	30	90	5
8	200	10	10	20	1	25	30	10
9	50	3	10	30	0,6	15	30	5
10	50	3	20	30	0,6	15	30	10
11	50	3	50	20	0,6	25	60	5
12	30	3	20	30	0,6	10	30	5
13	30	3	50	20	0,6	15	90	10
14	30	1	20	30	0,6	30	90	5
15	30	1	100	30	0,6	30	30	10
16	20	1	200	50	0,4	20	30	5
17	15	1	200	50	0,4	15	60	10
18	10	1	50	60	0,4	10	60	5
19	5	0,5	50	60	0,4	15	60	10
20	5	0,5	50	30	0,4	10	30	5
21	5	0,5	200	60	0,4	15	30	10

[a] The volume in this column is intended to be used for the selection of the test conditions and parameters based on the intended *tidal volume* of the *ventilator*.

[b] If the *end-expiratory flow* does not reach zero, reduce the *set rate* until it does.

c The rise time of the *ventilator* should be set to a value that ensures that the set pressure can be reached within the *inspiratory time*.

d For the purposes of this test, the set pressure is relative to set *BAP*.

201.12.1.103 Other *inflation-types*

a) If other *inflation-types* are provided, then with each other *inflation-type* selected and the *ventilator* operating in *normal condition*,

1) the performance at the *patient-connection port*; and

2) their acceptance criteria;

as determined by the *manufacturer*, shall be disclosed in the instructions for use.

3) The disclosed performance and acceptance criteria shall include the effects of the range of the *rated* input oxygen concentration.

b) All of the performance and acceptance criteria may be reported separately for the following ranges of intended *tidal volume*:

1) $V_{\text{tidal}} \geq 300$ ml;

2) 300 ml $\geq V_{\text{tidal}} \geq 50$ ml; and.

3) $V_{\text{tidal}} \leq 50$ ml.

c) The acceptance criteria of the performance of the *ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the instructions for use; or

2) determined for the worst-case *VBS* configuration indicated in the instructions for use.

NOTE The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.

In determining the worst-case configuration consider use with active and passive humidification.

d) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformity by inspection of the instructions for use, inspection of the risk management file for the rationale, if applicable, and with the tests specified by the manufacturer.

201.12.1.104 * *Inspiratory volume monitoring*

a) If the *ventilator* is equipped with *inspiratory volume monitoring equipment*, the accuracy of the *inspiratory volume monitoring equipment* shall be disclosed in the instructions for use.

b) For actual *tidal volumes* greater than 50 ml, the accuracy of the *inspiratory volume monitoring equipment* shall be within ±(4,0 +(15 % of the actual *inspiratory volume*)) ml.

Check conformity with the following.

Confirm that the inspiratory volume monitoring equipment accuracy as measured in 201.12.1.101 7) 7) and 201.12.1.102 f) 7) is within the accuracy disclosed in the instructions for use. For tidal volumes greater than 50 ml ensure that the accuracy disclosed in the instructions for use is ±(4,0 +(15 % of the actual inspiratory volume)) ml or better.

201.12.1.105 * Response of the *ventilator* to an increase in set O_2 concentration

a) The length of time required for the oxygen concentration in the *tidal volume* to change from a volume fraction of oxygen of 21 % to a volume fraction of 90 % of the maximum achievable volume fraction of oxygen shall be disclosed in the instructions for use.

b) The worst-case input oxygen concentration within the *rated* range shall be utilized for this test.

c) The time shall be reported separately, as appropriate, at *tidal volumes* for each intended *tidal volume* under the conditions of Table 201.106, using:

1) the worst-case *VBS;* or

2) the maximum internal volume *VBS* and

3) if base or *continuous flow* controls are provided, at:

   i) the minimum *bias flow*, or

   ii) the minimum *continuous flow*.

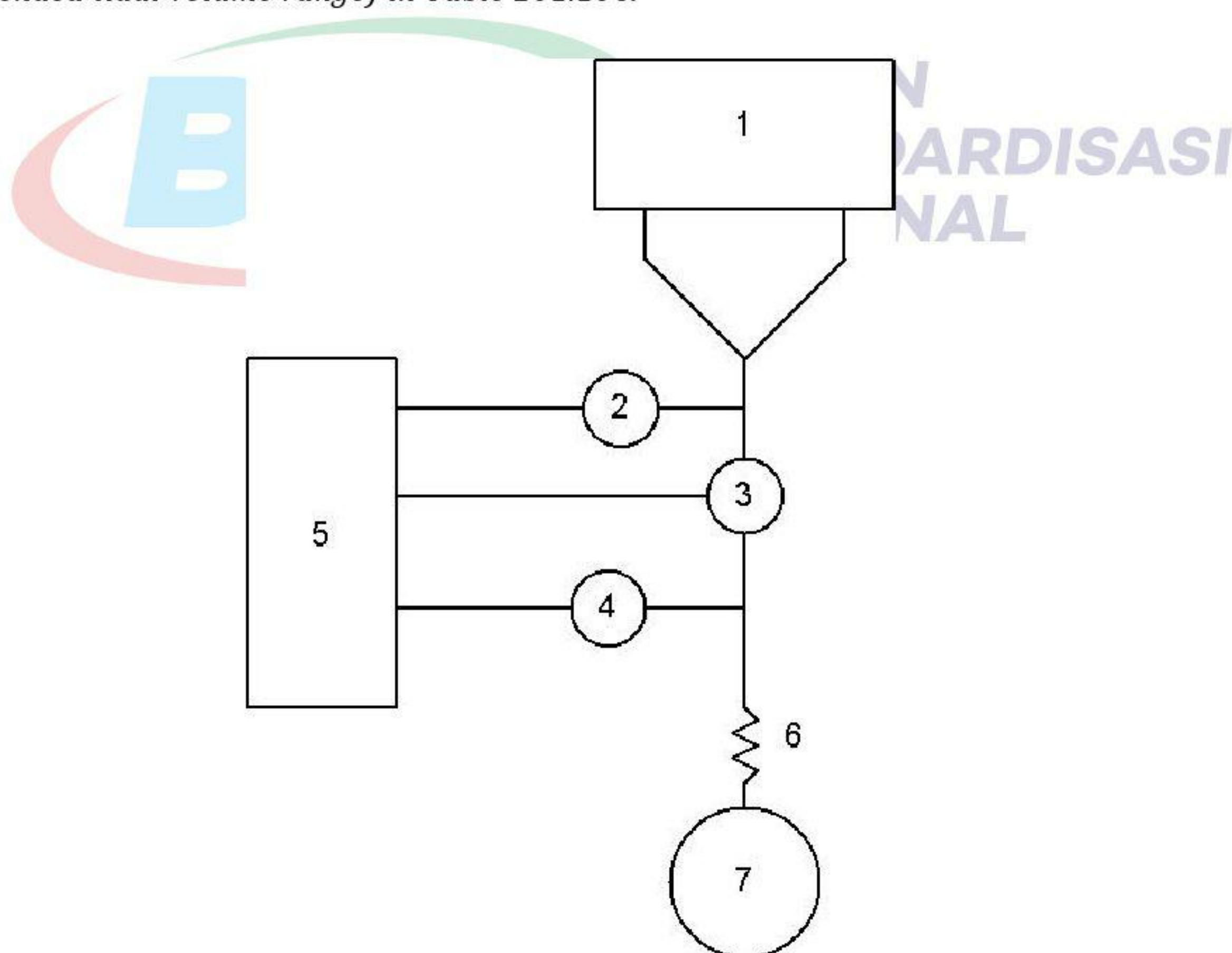
d) The time may be reported separately for:

1) each *VBS;* or

2) as a maximum (for the worst-case *VBS* and minimum *tidal volume*).

Check conformity with the following tests:

e) Set up the ventilator as shown in Figure 201.103 using the worst-case VBS or using the maximum internal volume VBS. If the VBS includes a humidifier, use the minimum humidifier water level indicated in the instructions for use.

f) Utilize the test conditions for the first applicable column available on the ventilator (selected by intended tidal volume range) in Table 201.106.

Key

1 *ventilator* under test

2 pressure sensor

3 flow sensor

4 oxygen sensor

5 data acquisition system

6 resistance

7 test lung

Figure 201.103 — O_2 concentration change test setup

Table 201.106 — Test conditions for O_2 concentration change tests

Adjustable parameter	**Test condition**		
	For a *ventilator* intended to provide *tidal volume*		
	$V_{tidal} \geq 300$ ml	300 ml $\geq V_{tidal} \geq$ 50 ml	$V_{tidal} \leq$ 50 ml
Tidal volume, V_{tidal}[a]	500 ml	150 ml	30 ml
Set rate	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1:2	1:2	1:2
Resistance, R[b][17][18][19]	5 hPa(l/s)$^{-1}$ ± 10 %	20 hPa(l/s)$^{-1}$ ± 10 %	50 hPa(l/s)$^{-1}$ ± 10 %

a V_{tidal} is determined by using the settings of the *ventilator*.

b The accuracy for R applies over the ranges of the measured parameters.

g) *Ventilate the test lung with a set oxygen concentration of 21 % volume fraction.*

h) *Wait until equilibrium is reached in the inspired oxygen concentration at the patient-connection port.*

i) *Change the set oxygen concentration to the maximum volume fraction that the ventilator permits.*

j) *Measure the time delay between setting the new concentration and achieving 90 % of the final oxygen concentration during inspiration at the patient-connection port. If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration. If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the inflation phase.*

k) *Ensure that the measured time delay is less than or equal to that indicated in the instructions for use.*

l) *Repeat g) to k) for each applicable column (selected by intended tidal volume range) in Table 201.106.*

m) *If the ventilator is provided with bias flow during the expiratory phase, repeat g) to l) at the minimum bias flow setting available on the ventilator.*

n) *If the ventilator is provided with continuous flow throughout the respiratory cycle, repeat g) to l) at the minimum continuous flowrate setting available on the ventilator.*

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 Oxygen monitor

a) The *ventilator* shall either

1) be equipped with O_2 *monitoring equipment* for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port)* that is integral to the *ventilator;* or

2) the instructions for use shall contain a statement to the effect that the *ventilator* is to be equipped with O_2 *monitoring equipment* for measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port)* before being put into service.

b) Such O_2 *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

4) 201.12.1.102;

5) 201.12.1.103; and

6) 208.6.1.2.

c) Where the O_2 *monitoring equipment* is not an integral part of the *ventilator*, the instructions for use shall include the following:

1) a statement to the effect that the *ventilator* is to be provided with O_2 *monitoring equipment* that conforms with ISO 80601-2-55:2018 before being put into service; and

2) information on where to connect the O_2 *monitoring equipment.*

d) The O_2 *monitoring equipment* shall, in addition, be equipped with an *alarm system* that includes a high oxygen level *alarm condition.*

e) The high oxygen level *alarm condition:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the high oxygen level *alarm condition* is suppressed or its priority is changed.

NOTE A low oxygen level *alarm condition* is required by ISO 80601-2-55.

Check conformity by inspection of the instructions for use or application of the tests of ISO 80601-2-55:2018.

201.12.4.102 * Measurement of *airway pressure*

a) The *ventilator* shall be equipped with *monitoring equipment* to measure the *airway pressure.*

b) The site of actual measurement:

1) may be anywhere in the *ventilator breathing system;* but

2) the indicated value shall be referenced to the *patient-connection port*.

c) Under steady-state conditions, the indicated *airway pressure* shall be accurate to within ±(2 +(4 % of the actual reading)) hPa (±(2 +(4 % of the actual reading)) cmH_2O).

Check conformity by functional testing.

201.12.4.103 * Measurement of expired volume and low volume *alarm conditions*

201.12.4.103.1 *Ventilators* intended to provide a *tidal volume* >50 ml

a) A *ventilator* intended to provide a *tidal volume* greater than 50 ml shall either:

1) be equipped with *monitoring equipment* for indicating the volume expired through the *patient-connection port;* or

2) if not so equipped, the instructions for use shall include a statement to the effect that the *ventilator* is to be equipped with *monitoring equipment* that conforms with this document before being put into service.

If equipped,

b) unless the expired volume *monitoring equipment* is an integral part of the *ventilator*, information on where to connect the expired volume *monitoring equipment* shall be disclosed in the instructions for use.

c) the accuracy of measurement of expired volumes greater than 50 ml shall be within ±(4,0 +(15 % of the actual volume expired through the *patient-connection port*)) ml.

d) the accuracy of expired volume *monitoring equipment* shall be disclosed in the instructions for use.

e) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

NOTE The use of Oxygen 93 % can reduce the accuracy of measurement due to influence of other gases such as argon on flow measurement.

f) the expired volume *monitoring equipment* shall be equipped with an *alarm system* to indicate when:

1) the low expired volume *alarm limit* is reached*;* and

2) the high expired volume *alarm limit* is reached.

g) the low expired volume and the high expired volume *alarm conditions:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that

i) the low expired volume or

ii) the high expired volume *alarm condition*

is suppressed or its priority is changed.

h) the expired volume *monitoring equipment* may be equipped with an *alarm system* that:

   1) starts with *low priority alarm conditions* to indicate when the expired volume reaches either *alarm limit;* and

   2) if this state continues, escalates to *medium priority alarm conditions.*

i) the expired volume *alarm limits* may be:

   1) pre-adjusted;

   2) *responsible organization*-adjustable;

   3) *healthcare professional operator*-adjustable;

   4) *ventilator*-adjustable; or

   5) a combination of *healthcare professional operator*-adjustable and *ventilator*-adjustable.

j) if the *alarm limits* are adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the instructions for use.

   NOTE Depending on the type of *ventilation-mode* being utilized, there can be more than one active *alarm limit.*

Check conformity by functional testing using the test conditions described in Table 201.104 and Table 201.105 selecting the appropriate rows based on intended tidal volume and inspection of the instructions for use. Select and set up the worst-case VBS configuration indicated in the instructions for use.

EXAMPLE Minimum or maximum *VBS* compliance.

For testing with a humidifier, repeat the tests at the minimum and maximum water levels (2 sets of tests for a humidifier).

201.12.4.103.2 *Ventilators* intended to provide a *tidal volume* ≤50 ml

a) If a *ventilator* is intended to provide a *tidal volume* ≤50 ml, it may be equipped with expired volume *monitoring equipment.*

b) The accuracy of the expired volume *monitoring equipment* at an expired volume ≤50 ml shall be disclosed in the instructions for use.

c) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

   NOTE 1 The use of Oxygen 93 % can reduce the accuracy of measurement due to influence of other gases such as argon on flow measurement.

d) The expired volume *monitoring equipment* may be equipped with an *alarm system* to indicate when the expired volume reaches the low expired volume *alarm limit.*

e) The low expired volume *alarm condition:*

1) shall be at least *low priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that:

i) the low expired volume *alarm condition* is suppressed; or

ii) its priority is changed.

f) If provided, the expired volume *alarm limit* may be:

1) pre-adjusted;

2) *responsible organization*-adjustable;

3) *healthcare professional operator*-adjustable;

4) *ventilator*-adjustable; or

5) a combination of *healthcare professional operator*-adjustable and *ventilator*-adjustable.

g) If the *alarm limit* is adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the instructions for use.

NOTE 2 Depending on the type of *ventilation-mode* being utilized, there can be more than one active *alarm limit.*

Check conformity by functional testing using the test conditions described in Table 201.104 and Table 201.105 selecting the appropriate rows based on intended tidal volume and inspection of the instructions for use. Select and set up the worst-case VBS configuration indicated in the instructions for use.

EXAMPLE Minimum and maximum *VBS* compliance.

For testing with a humidifier, repeat the tests at minimum and maximum water levels (2 sets of tests for a humidifier).

201.12.4.104 * Expiratory end-tidal CO_2 *monitoring equipment*

a) If a *ventilator* intended to provide a *tidal volume* ≤50 ml is not equipped with expired volume *monitoring equipment* (see 201.12.4.103.2), the *ventilator* shall either:

1) be equipped with CO_2 *monitoring equipment* for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port)* that is integral to the *ventilator;* or

2) the instructions for use shall contain a statement to the effect that the *ventilator* is to be equipped with CO_2 *monitoring equipment* for the measurement of the expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port)* before being put into service.

b) Such CO_2 *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

4) 201.12.1.102;

5) 201.12.1.103; and

6) for expired CO_2 concentration, 208.6.1.2.

c) Where the CO_2 *monitoring equipment* is not an integral part of the *ventilator*, the instructions for use shall include the following:

1) a statement to the effect that the *ventilator* is to be provided with CO_2 *monitoring equipment* that conforms with ISO 80601-2-55:2018 before being put into service; and

2) information on where to connect the CO_2 *monitoring equipment*.

Check conformity by inspection.

201.12.4.105 * *Maximum limited pressure protection device*

a) A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* under both:

1) *normal condition*; and

2) *single fault condition*.

b) The *maximum limited pressure* shall not exceed the lower of:

1) 20 hPa (20 cmH_2O) more than the high pressure *alarm limit; or*

2) 125 hPa (125 cmH_2O).

NOTE See also 201.12.4.106 and 201.12.4.110.

Check conformity by functional testing.

201.12.4.106 * High *airway pressure alarm condition* and *protection device*

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* to indicate when the high-pressure limit for *airway pressure* is reached.

b) The high *airway pressure alarm condition:*

1) shall be *high priority*; unless

2) an *intelligent alarm system*, based on additional information, determines that:

i) the high *airway pressure alarm condition* is suppressed; or

ii) its priority is changed.

c) The high *airway pressure alarm limit* may be:

1) independently adjustable; or

2) related to the set pressure of the *ventilator*.

d) It shall not be possible to set the high-*airway pressure alarm limit* to a value greater than the *maximum limited pressure* limit.

e) * Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm the setting of the high-pressure *alarm limit* to values exceeding the lower of:

1) 20 hPa (20 cmH_2O) more than the *operator*-set pressure; or

NOTE The *operator*-set pressure does not apply when by design the *ventilator* adjusts the *airway pressure* on a breath-by-breath basis.

2) 60 hPa (60 cmH_2O).

f) * *Patient*-generated transient pressure increases should not cause the high-pressure *alarm condition*.

EXAMPLE A transient pressure increase caused by the *patient* coughing.

g) The high *airway pressure alarm condition delay* shall not exceed 200 ms and the *ventilator* shall:

1) act to attempt to cause the pressure to start to decline within that duration; and

2) act to prevent the pressure from continuing to rise.

h) * Whenever the high-pressure *alarm condition* occurs, the *ventilator* shall, within no more than two *respiratory cycles* or 15 s, whichever is less, reduce the *airway pressure* to either:

1) the atmospheric pressure; or

2) the set *BAP* level.

i) During *single fault condition*, the *airway pressure* may fall below the set *BAP* level.

Check conformity by functional testing.

201.12.4.107 *PEEP alarm conditions*

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate when the end-expiratory pressure is above the high *PEEP alarm limit*.

b) The *ventilator* may be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate when the end-expiratory pressure is below the low *PEEP alarm limit*.

c) Both the high and low *PEEP alarm conditions:*

1) shall be of at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information determines that the high or low *PEEP alarm condition*:

i) is suppressed; or

ii) the priority is changed.

d) The *alarm condition delay* for high *PEEP alarm condition* shall not exceed the duration of three *inflations*.

Check conformity by functional testing with every VBS indicated in the instructions for use.

NOTE To perform this test, modification of the ventilator to disable the BAP control can be required.

201.12.4.108 * Obstruction *alarm condition*

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects a *technical alarm condition* to indicate when the *alarm limit* for obstruction is reached.

EXAMPLE *Alarm condition* to warn of:
— an obstructed inspiratory or expiratory breathing tube;
— a blocked exhalation valve; or
— a blocked expiratory *breathing system filter.*

b) The obstruction *technical alarm condition:*

1) shall be *high priority*, unless

2) an *intelligent alarm system*, based on additional information, determines that the obstruction *technical alarm condition:*

i) is suppressed; or

ii) its priority is changed.

c) The *alarm condition delay* shall not exceed more than

1) two *respiratory cycles* or

2) 5 s,

whichever is greater.

d) Whenever the obstruction *alarm condition* occurs, the *ventilator* shall, within no more than one *respiratory cycle*, reduce the *airway pressure* to either:

1) atmospheric pressure; or

2) the set *BAP* level.

e) The *ventilator* should be equipped with a *protection device* to allow spontaneous breathing when obstruction occurs.

f) If equipped with the *protection device*, the pressure drop measured at the *patient-connection port*, with all recommended *accessories* in place, shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

1) 30 l/min for a *ventilator* intended to provide *tidal volume*, $V_{tidal} \geq 300$ ml;

2) 15 l/min for a *ventilator* intended to provide *tidal volume*, 300 ml $\geq V_{tidal} \geq 50$ ml; and

3) 2,5 l/min for a *ventilator* intended to provide *tidal volume*, $V_{tidal} \le 50$ ml.

g) The *accompanying document* shall describe:

1) the means by which the obstruction *alarm condition* is determined; and

2) a means to test the obstruction *alarm condition*.

Check conformity by functional testing with each VBS indicated in the instructions for use, according to the test method described in the accompanying document.

201.12.4.109 * Disconnection *alarm condition*

a) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for disconnection.

NOTE Disconnection can be detected using one or more means, for example measurement of pressure at the *ventilator gas output port*, measurement of flow at the exhalation valve or measurement of expired flow or end-tidal CO_2 at the *patient-connection port*.

b) The disconnection *technical alarm condition* shall be at least *medium priority*.

c) The *alarm off* or *audio off* of the disconnection *technical alarm condition alarm signals* shall not be provided when the *ventilator* is operating in any *ventilator-operational mode* intended for a *ventilator-dependent patient*.

d) The *alarm off* or *audio off* of the disconnection *technical alarm condition alarm signals* may be provided when the *ventilator* is operating in any *ventilator-operational mode* not intended for a *ventilator-dependent patient*.

e) The instructions for use shall disclose the maximum *alarm condition delay* of the disconnection *technical alarm condition*.

f) The instructions for use shall disclose any use scenarios in which decannulation might not be detected as a *VBS* disconnection.

EXAMPLE For a neonatal *ventilator* normally intended to be used with a flow sensor placed between the *patient-connection port* and the tracheal tube, use of the *ventilator* with the flow sensor disconnected.

Check conformity by functional testing and inspection of the instructions for use.

201.12.4.110 Protection against inadvertent setting of high *airway pressure*

Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm any *airway pressure* settings exceeding 60 hPa (60 cmH_2O). See also 201.12.4.105 b) and 206.101 a) 7).

Check conformity by functional testing.

201.12.101* Protection against accidental or unintentional adjustments

a) The *ventilator* shall include a means for the *healthcare professional operator* to confirm the *ventilation-mode* and settings:

1) during the start-up *procedure*; and

2) when the *ventilation-mode* is changed during use.

b) Means of protection shall be provided against accidental or unintentional adjustment of controls that can create a *hazardous situation*, including against accidently turning the *ventilator* off.

c) The *usability* of these means of protection shall be evaluated in the *usability engineering process*.

NOTE The requirements for the *usability engineering process* are found in IEC 60601-1:2005+AMD1:2012, 12.2 and IEC 60601-1-6:2010+AMD1:2013.

Check conformity by functional testing and inspection of usability engineering file.

201.13 *Hazardous situations* and fault conditions for *ME equipment*

Clause 13 of the general standard applies, except as follows:

Addition:

201.13.2.101 * Additional specific *single fault conditions*

A *ventilator* shall be so designed and constructed that the following *single fault conditions* shall not cause an unacceptable *risk*:

a) * disruption of the gas delivery to the *patient-connection port* from the *ventilator*;

b) * when present, disruption of the gas flow pathway from the *patient-connection port* to the *ventilator;*

c) * removal or failure of a *healthcare professional operator*-detachable *breathing system filter*; and

d) * disruption of a *functional connection* between parts of the *ventilator* or *ME system*.

EXAMPLE 1 Loss of communication between the *ventilator* and its remote (wired or wireless) control or monitoring module.

EXAMPLE 2 Loss of communication between the *ventilator* and its *distributed alarm system.*

Check conformity by functional testing and inspection of risk management file.

201.13.2.102 * Failure of one gas supply to a *ventilator*

a) Following the failure of one gas supply connected to a *high-pressure input port*, a *ventilator* shall maintain *normal use*.

b) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this gas supply failure.

c) The gas supply failure *technical alarm condition:*

1) shall be at least *low priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the gas supply failure *technical alarm condition* is suppressed.

Check conformity by functional testing.

201.13.2.103 * Independence of ventilation control function and related *risk control* measures

a) A *single fault condition* shall not cause the simultaneous failure of:

1) a ventilation control function; and

2) the corresponding *protection device*.

b) A *single fault condition* shall not cause either:

1) a ventilation control function and the corresponding *monitoring equipment*; or

2) a ventilation control function and the corresponding *alarm system*

to fail in such a way that the loss of the ventilation control function is not detected.

Check conformity by inspection and functional testing.

201.13.2.104 * Failure of *functional connection* to a *ventilator* control or monitoring means

a) Following the failure of a *functional connection* to a *ventilator* control or monitoring means, the *ventilator* shall continue to ventilate the *patient*.

b) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this communication failure.

c) The communication failure *technical alarm condition:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the communication failure *technical alarm condition:*

i) is suppressed; or

ii) the priority is changed.

Check conformity by functional testing.

201.14 *Programmable electrical medical systems (PEMS)*

Clause 14 of the general standard applies, except as follows:

Addition:

201.14.101 Software life cycle

a) The *programmable electronic subsystems* (*PESS*) of a *ventilator* shall be developed with a design *process* conforming with IEC 62304:2006+AMD1:2015.

b) The ventilation control *software items* of the *ventilator PESS* without an independent *risk control* measure external to the *PESS* shall be considered as software safety Class C.

Check conformity by inspection of the documentation required by IEC 62304:2006+AMD1:2015 for the software safety class (the requirements are found in 1.4 of IEC 62304:2006+AMD1:2015).

201.15 Construction of *ME equipment*

Clause 15 of the general standard applies, except as follows:

Addition:

201.15.3.5.101 Additional requirements for rough handling

201.15.3.5.101.1 * Shock and vibration (robustness)

a) A *ventilator* and its parts, including applicable *accessories* shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling.

b) *Stationary ME equipment* is exempt from the requirements of this subclause.

c) After the following tests, the *ventilator* shall:

1) maintain *basic safety* and *essential performance*; and

2) conform with the requirements of 201.12.1 and 201.12.4.

NOTE 1 A *ventilator* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

Conformity is checked by performing the following tests:

d) Shock test in conformance with IEC 60068-2-27:2008, using the following conditions:

NOTE 2 This represents IEC/TR 60721-4-7:2001[24], Class 7M2.

1) test type: Type 1:

- *peak acceleration: 150 m/s² (15 g);*
- *duration: 11 ms;*
- *pulse shape: half-sine; and*
- *number of shocks: 3 shocks per direction per axis (18 total);*

or

2) *test type: Type 2:*

— *peak acceleration: 300 m/s^2 (30 g);*

— *duration: 6 ms;*

— *pulse shape: half-sine; and*

— *number of shocks: 3 shocks per direction per axis (18 total).*

e) *Broadband random vibration test in conformance with IEC 60068-2-64:2008, using the following conditions:*

NOTE 3 This represents IEC/TR 60721-4-7:2001[24], Classes 7M1 and 7M2, modified.

1) *acceleration amplitude:*

— *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz; and*

— *100 Hz to 500 Hz: –6 db per octave;*

2) *duration: 10 min per perpendicular axis (3 total).*

f) *Confirm that basic safety and essential performance and the requirements of 201.12.1 and 201.12.4 are maintained following the tests.*

201.15.3.5.101.2 * Shock and vibration for a *transit-operable ventilator* during operation

a) A *ventilator* and its parts, including applicable *accessories*, intended for *transit-operable* use (during *patient* transport inside a healthcare facility) shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling while operating.

b) For this test, the *ventilator* and its parts, and applicable *accessories*, shall be mounted using the mounting *accessories* indicated in the *accompanying documents*.

If more than one mounting system is described in the *accompanying documents*, multiple tests are required.

NOTE A *ventilator* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

c) During the following test, a *ventilator* shall maintain *basic safety* and *essential performance* while ventilating a test lung using the worst-case conditions and parameters of Table 201.102, selected by intended *tidal volume*, as appropriate.

d) Perform the tests with a *volume-control inflation-type* or a *pressure-control inflation-type*, as applicable.

e) For *volume-control inflation-types*, during the testing, the error of:

1) the *inspiratory volume* of individual *inflations* shall not deviate by more than 35 % of the *inspiratory volume* measured prior to the test;

2) the *inspiratory volume* averaged over a one min interval shall not deviate by more than 25 % of the *inspiratory volume* measured prior to the test;

3) the *PEEP* of individual *inflations* shall not deviate by more than 5,0 hPa (5,0 cmH_2O) from the *PEEP* measured prior to the test; and

4) the delivered FiO_2 (inspiratory oxygen concentration) averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the instructions for use.

f) For *pressure-control inflation-types*, during the testing, the error at the *patient-connection port:*

1) of the pressure of the individual *inflations* shall not deviate by more than 35 % of the pressure measured prior to the test;

2) of the pressure averaged over a one min interval shall not deviate by more than 25 % of the pressure measured prior to the test;

3) of the *PEEP* of individual *inflations* shall not deviate by more than 5,0 hPa (5,0 cmH_2O) from the *PEEP* measured prior to the test; and

4) of the delivered FiO_2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the instructions for use.

g) During this testing, the *alarm limits* for volume and pressure *alarm conditions* shall be set to their least sensitive levels.

Check conformity by performing the following tests:

h) Shock test in conformance with IEC 60068-2-27:2008, using the following conditions:

1) test type: Type 1:

— *peak acceleration: 50 m/s² (5 g);*

— *duration: 6 ms;*

— *pulse shape: half-sine; and*

— *number of shocks: 3 shocks per direction per axis (18 total).*

i) Broadband random vibration test in conformance with IEC 60068-2-64:2008, using the following conditions:

1) acceleration amplitude:

— *10 Hz to 100 Hz: 0,33 $(m/s^2)^2/Hz$; and*

— *100 Hz to 500 Hz: −6 db per octave;*

2) duration: 30 min per perpendicular axis (3 total).

j) Free fall in conformance with IEC 60068-2-31:2008, using Procedure 1 and the following conditions:

1) fall height:

i) for mass ≤ 1 kg, 0,25 m;

ii) for mass > 1 kg and ≤ 10 kg, 0,1 m;

iii) for mass > 10 kg and ≤ 50 kg, 0,05 m; and

iv) for mass > 50 kg, 0,01 m

2) number of falls: 2 in each specified attitude.

k) Confirm that during these tests:

1) basic safety is maintained;

2) for volume-control inflation-types, the inspiratory volume, PEEP and delivered FiO_2 are within the indicated limits during the tests; and

3) for pressure-control inflation-types, the pressure, PEEP and delivered FiO_2 are within the indicated limits during the tests.

201.15.4.1 Construction of connectors

Addition:

aa) *Healthcare professional operator*-detachable *gas pathway* connectors are exempt from this requirement.

201.15.101 Mode of operation

A *ventilator* shall be suitable for *continuous operation*.

Check conformity by inspection.

201.15.102 Delivered oxygen concentration

A *ventilator* shall be capable of supplying gas with an O_2 concentration over the range from ambient to at least 95 % of the input oxygen concentration to the patient.

Check conformity by functional testing.

201.15.103 *Accessory* self-check

a) A *ventilator* shall be equipped with means that allow the determination of whether or not the *VBS* resistance and compliance characteristics fall outside the values necessary to maintain normal operation.

NOTE Additional requirements are found in 201.7.9.2.8.101.

b) This means may require *operator* action.

Check conformity by functional testing.

201.16 *ME systems*

Clause 16 of the general standard applies, except as follows:

Addition:

201.16.1.101 Additional general requirements for *ME systems*

Accessories connected to the *VBS* shall be considered to

a) be part of the *ventilator;* or

b) form an *ME system* with the *ventilator*.

Check conformity by application of the relevant tests of this document and IEC 60601-1:2005+AMD1:2012.

201.16.2.101 * Additional general requirements for *accompanying documents* of an *ME system*

Amendment (add after list element c)):

100) If applicable, a description of the *use scenarios* and ranges of ventilation settings over which elevated temperature of the gas at the *ventilator gas output port* can lead to the failure of a respiratory gas *humidifier* to function according to its specification.

EXAMPLE A blower/turbine-based ventilator operating with ventilator settings that result in the delivered breathing gas temperature exceeding 27 °C can cause the humidifier to reduce humidity output below the lower limit allowed by ISO 80601-2-74.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

Clause 17 of the general standard applies.

Addition:

201.101 Gas connections

201.101.1 * Protection against reverse gas leakage

For a *ventilator* with two or more *high-pressure input ports*,

a) means shall be provided to limit reverse gas flowrate (leakage) from *gas intake ports* into the supply system of the same gas to a flowrate less than 100 ml/min in *normal condition* or *single fault condition*.

b) means shall be provided to limit cross leakage from gas supplied through one *high-pressure input port* into the supply system of a different gas to less than 100 ml/h in *normal condition* or *single fault condition*.

Check conformity by functional testing.

201.101.2 Connection to a *high-pressure input port*

201.101.2.1 Connector

If an *operator*-detachable hose assembly is provided for connection between the *ventilator* and either a *medical gas pipeline system* or a pressure regulator, it shall conform with ISO 5359:2014.

Check conformity by application of the tests of ISO 5359:2014.

201.101.2.2 * Filter

Each *high-pressure input port* shall be provided with a filter having a pore size less than or equal to 100 μm.

NOTE 1 The need for particle filtration in oxygen-enriched environments including the proper choice of filter materials is discussed in ISO 15001:2010[8].

NOTE 2 Depending on the sensitivity against particles of the components used in the *gas pathways* (e.g. flow sensors) to particles, filtration of smaller particles can be needed.

Check conformity by inspection.

201.101.3 *VBS* connectors

201.101.3.1 * General

Operator-detachable *VBS* connections through which the main flow of gas to or from the *patient* passes in *normal condition*, excluding the *patient-connection port*:

a) shall be a 15 mm or a 22 mm connector conforming with ISO 5356-1:2015;

b) may be a 11,5 mm connector conforming with ISO 5356-1:2015 for a neonatal or paediatric use *VBS*; or

c) may be a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.3.2 Other named ports

201.101.3.2.1 *Patient-connection port*

The *patient-connection port* shall be one of the following:

a) a female 15 mm conical connector conforming with ISO 5356-1:2015; or

b) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015.

201.101.3.2.2 *Gas output port* and *gas return port*

a) The *gas output port* and the *gas return port* shall be one of the following

1) a male 22 mm conical connector conforming with ISO 5356-1:2015.

2) a male 15 mm conical connector conforming with ISO 5356-1:2015.

3) a coaxial 15 mm/22 mm conical connector conforming with ISO 5356-1:2015.

4) a non-conical connector that does not engage with a conical connector conforming with ISO 5356-1:2015.

b) Notwithstanding this requirement, a *ventilator* only intended for *tidal volumes* of ≤300 ml, may be equipped with a *gas output port* and a *gas return port* using a male 11,5 mm conical connector conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015.

201.101.3.2.3 *Emergency intake port*

a) An *emergency intake port* shall not be equipped with an *operator*-accessible connector.

b) An *emergency intake port* shall be designed to prevent obstruction when the *ventilator* is in use.

Check conformity by inspection.

201.101.3.2.4 *Flow-direction-sensitive components*

Any *flow-direction-sensitive component* of the *VBS* detachable without the use of a *tool* shall be so designed that it cannot be fitted in such a way that it presents an unacceptable *risk* to the *patient*.

Check conformity by inspection of detachable flow-direction-sensitive components and inspection of the risk management file.

201.101.3.2.5 * *Accessory* port

If provided, each *accessory* port shall:

a) conform with ISO 80369-1:2018;

b) be provided with a means to secure the *accessory* in position; and

c) be provided with a means to secure closure after removal of the *accessory*.

NOTE 1 This port connects to the *gas pathway* and is generally used for measuring pressure or for the introduction of therapeutic aerosols.

NOTE 2 For the purposes of this document, the temperature probe port specified in ISO 80601-2-74 is not considered an *accessory* port.

Check conformity by inspection.

201.101.3.2.6 Gas *exhaust port*

a) If a connector is provided for the gas *exhaust port*, it shall be a 30 mm connector conforming with ISO 5356-1:2015.

NOTE A 30 mm connector conforming with ISO 5356-1:2015 is suitable for connection to *anaesthesia gas scavenging system* (AGSS) that conforms with ISO 80601-2-13[2].

b) A *ventilator* shall be designed so that any provided gas *exhaust port* is not obstructed during use.

Check conformity by inspection and application of the tests of ISO 5356-1:2015.

201.101.3.2.7 Temperature sensor port

The *VBS* may be equipped with a temperature sensor port conforming with 201.101.8 of ISO 80601-2-74:2017.

201.102 Requirements for the *VBS* and *accessories*

201.102.1 * General

All *ventilator breathing systems*, their parts and *accessories* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *ventilator* or by another entity ("third-party manufacturer" or healthcare provider).

Check conformity by the tests of this document.

201.102.2 Labelling

a) The *accompanying document* provided with each *VBS*, its parts or *accessories*, conforming with 201.102.1, shall include at least the *model or type reference* of at least one compatible *ventilator*.

b) Statements shall be included in the *accompanying document* of each *ventilator breathing system*, its parts or *accessories* to the effect that:

   1) ventilator breathing systems, their parts and accessories are validated for use with specific ventilators;

   2) incompatible parts can result in degraded performance; and

   3) the responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.

Check conformity by inspection of the accompanying document.

201.102.3 Breathing tubes

Breathing tubes intended for use in the *VBS* shall conform with the following clauses and subclauses of ISO 5367:2014:

a) 5.1;

b) 5.3.4;

c) Clause 6; and

d) Clause 7.

Check conformity by application of the tests of ISO 5367:2014.

201.102.4 * Water vapour management

201.102.4.1 Humidification system

Any *humidifier*, including heated breathing tubes, either incorporated into the *ventilator* or recommended for use with the *ventilator*, shall conform with ISO 80601-2-74:2017.

Check conformity by application of the tests of ISO 80601-2-74:2017.

201.102.4.2 *Heat and moisture exchanger* (*HME*)

Any *heat and moisture exchanger*, either incorporated into the *VBS* or recommended for use with the *VBS*, shall conform with:

a) ISO 9360-1:2000; or

b) ISO 9360-2:2001.

Check conformity by application of the tests of ISO 9360-1:2000 or ISO 9360-2:2001.

201.102.6 *Breathing system filters*

Any *breathing system filter*, either incorporated into the *ventilator* or recommended for use with the *ventilator*, shall conform with the relevant requirements of:

a) ISO 23328-1:2003; and

b) ISO 23328-2:2002.

Check conformity by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.102.7 *Ventilator breathing systems*

201.102.7.1 * Leakage from complete *VBS*

Unintended leakage from the *VBS* should not exceed:

a) 200 ml/min at 50 hPa (50 cmH_2O) for a *ventilator* intended to provide a *tidal volume* greater than 300 ml;

b) 100 ml/min at 40 hPa (40 cmH_2O) for a *ventilator* intended to provide a *tidal volume* between 300 ml and 50 ml; or

c) 50 ml/min at 20 hPa (20 cmH_2O) for a *ventilator* intended to provide a *tidal volume* less than 50 ml.

201.102.7.2 * Non-invasive ventilation

a) The instructions for use for a *ventilator* intended for non-invasive ventilation shall include a warning statement to the effect that the exhaled volume and exhaled CO_2 of the *patient* can differ from the measured exhaled volume and exhaled CO_2 due to leaks around the *mask*.

b) A *ventilator* intended for non-invasive ventilation should either:

   1) be equipped with CO_2 *monitoring equipment* for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the *patient-connection port)* in accordance with ISO 80601-2-55; or

   2) if not so equipped, the instructions for use should contain a statement to the effect that the *ventilator* is to be provided with CO_2 *monitoring equipment* for the measurement of expiratory carbon dioxide concentration, (e.g. in the expiratory limb or at the *patient-connection port)* in accordance with ISO 80601-2-55 before being put into service.

Check conformity by inspection of the instructions for use or application of the tests of ISO 80601-2-55:2018.

201.103 * Spontaneous breathing during loss of power supply

a) A *protection device* shall be provided to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.

b) Under these conditions, the inspiratory and expiratory pressure drop measured at the *patient-connection port* with all recommended *accessories* in place shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

   1) 30 l/min for a *ventilator* intended to provide a *tidal volume,* $V_{tidal} \geq 300$ ml;

   2) 15 l/min for a *ventilator* intended to provide a *tidal volume,* 300 ml $\geq V_{tidal} \geq$ 50 ml;

   3) 2,5 l/min for a *ventilator* intended to provide a *tidal volume,* $V_{tidal} \leq 50$ ml.

NOTE These requirements are intended to allow the *patient* to breathe spontaneously under compromised conditions.

Check conformity by functional testing and measurement of flowrate, pressure, and resistance at the patient-connection port with that combination of accessories indicated in the instructions for use which produces the highest pressure drop.

201.104 * Indication of duration of operation

a) The *ventilator* shall have means to indicate visually the cumulative hours of operation of the *ventilator*, either:

   1) automatically; or

2) by *operator* action.

b) The *ventilator* should also have means to indicate visually:

1) the time since the last preventive maintenance; or

2) the time until the next recommended preventive maintenance.

Check conformity by inspection.

201.105 *Functional connection*

201.105.1 General

Basic safety and *essential performance* shall be maintained if connections to a *functional connection* of a *ventilator* are:

a) disrupted; or

b) if the equipment connected to those parts fails.

Check conformity by functional testing.

201.105.2 * Connection to an electronic health record

a) A *ventilator* shall be equipped with a *functional connection* that permits data transmission from the *ventilator* to an electronic health record.

b) The data transmission should be capable of transmitting the information described in Annex BB.

Check conformity by inspection.

201.105.3 * Connection to a *distributed alarm system*

A *ventilator* shall be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

201.105.4 Connection for remote control

A *ventilator* may be equipped with a *functional connection* for connection for external control of the *ventilator*.

NOTE ASTM F2761-09[26] is an example of a suitable standard for providing such a *functional connection.*

201.106 Display loops

201.106.1 Pressure-volume loops

a) If a *ventilator* is provided with the display of pressure-volume loops the graph shall use:

1) *inspiratory volume* on the vertical axis; and

2) *airway pressure* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Increases in *inspiratory volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

Check conformity by inspection.

201.106.2 Flow-volume loops

a) If a *ventilator* is provided with the display of flow-volume loops, the graph shall use:

1) flowrate on the vertical axis; and

2) *inspiratory volume* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Gas flow to the *patient* (inspiratory flow) and increases in *inspiratory volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

e) The *ventilator* may be provided with an additional optional display configuration for the flow-volume loop where gas flow from the *patient* (expiratory flow) is represented as a positive value.

Check conformity by inspection.

201.107 * Timed ventilatory pause

201.107.1 *Expiratory pause*

a) A *ventilator* may be equipped with a *healthcare professional operator*-controlled means to pause the *ventilator* in expiration.

b) If a *ventilator* is equipped with a means to pause the *ventilator* in expiration,

1) more than one *expiratory pause* function may be provided.

2) the maximum allowable duration of an *expiratory pause* shall be 60 s.

3) means may be provided to initiate the *expiratory pause* from a *functional connection*.

c) If a *ventilator* is equipped with a timed means to pause the *ventilator* in expiration,

1) the duration of the *expiratory pause* may be *operator*-configurable or *operator*-adjustable.

2) during the *expiratory pause*, any apnoea-related ventilatory *alarm condition* that would be caused by this *expiratory pause* shall be *audio paused* or *alarm paused* for the duration of the *expiratory pause*.

3) in addition to the requirements for *alarm signal* inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the *ventilator* shall indicate the presence of the *expiratory pause* with at least an *information signal* or a *low priority alarm condition*.

NOTE 1 An *expiratory pause* can be equivalent to placing the *ventilator* into standby mode or *CPAP* and automatically resuming ventilation after a pre-determined duration.

NOTE 2 The *expiratory pause* can be used to synchronize radiographic imaging with deflated lungs.

Check conformity by inspection and functional testing.

201.107.2 *Inspiratory pause*

a) A *ventilator* may be equipped with a *healthcare professional operator*-controlled means to pause automatic ventilation at end-inspiration.

b) If a *ventilator* is equipped with a means to pause the *ventilator* in inspiration,

1) more than one *inspiratory pause* function may be provided;

2) the maximum duration of a non-adjustable *inspiratory pause* shall be 10 s;

3) the maximum allowable duration of an adjustable *inspiratory pause* shall be 40 s; and

4) means may be provided to initiate the *inspiratory pause* from a *functional connection*.

c) If a *ventilator* is equipped with a timed means to pause the *ventilator* in inspiration,

1) the duration of the *inspiratory pause* may be non-adjustable, *responsible organization*-configurable or *operator*-adjustable.

2) the high-pressure *alarm condition* and *protection device* of 201.12.4.105 shall remain active during an *inspiratory pa*use.

3) during the *inspiratory pause*, any:

i) apnoea *alarm condition;* or

ii) sustained *airway pressure alarm condition*

that would be caused by this *inspiratory pause* should, for the duration of the *inspiratory pause*, be:

iii) *audio paused*; or

iv) *alarm paused*.

d) In addition to the requirements for *alarm signal* inactivation in 6.8.5 of IEC 60601-1-8:2006+AMD1:2012, the *ventilator* shall indicate the presence of the *inspiratory pause* with

1) at least an *information signal;* or

2) a *low priority alarm condition*.

NOTE The *inspiratory pause* can be used to synchronize radiographic imaging with lung *inflation* or used for a recruitment manoeuvre (a temporary increase in pressure intended to expand the lung).

Check conformity by inspection and functional testing.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.4.3.1 * Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

— the *ventilator* operated using the worst-case conditions and parameters of Table 201.104 or Table 201.105, selected by intended *tidal volume*, as appropriate. During this testing, set the volume and pressure *alarm condition alarm limits* to their least sensitive levels.

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 * Additional general requirements

a) The following degradations, if associated with *basic safety* and *essential performance*, shall not be allowed:

1) component failures;

2) changes in programmable parameters or settings;

3) reset to default settings;

4) change of *ventilation-mode*;

EXAMPLE Change of *inflation-type, set rate, I:E ratio.*

5) initiation of an unintended operation;

6) For *volume-control inflation-types*, during the testing, the error of*:*

i) *inspiratory volume* of individual *inflations* shall not deviate by more than 35 % of the *inspiratory volume* measured prior to the test;

ii) *inspiratory volume* averaged over a one min interval shall not deviate by more than 25 % of the *inspiratory volume* measured prior to the test;

iii) *PEEP* of individual *inflation*s shall not deviate by more than 5 hPa (5,0 cmH_2O) from the *PEEP* measured prior to the test; and

iv) of the delivered FiO_2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the instructions for use.

7) For *pressure-control inflation-types*, during the testing, the error at the *patient-connection port:*

   i) of the pressure of individual *inflation*s shall not deviate by more than 35 % of the pressure measured prior to the test;

   ii) of the pressure averaged over a one min interval shall not deviate by more than 25 % of the pressure measured prior to the test;

   iii) of *PEEP* of individual *inflation*s shall not deviate by more than 5 hPa (5,0 cmH_2O) from the *PEEP* measured prior to the test; and

   iv) of the delivered FiO_2 averaged over a one min interval shall not deviate by more than the deviation disclosed by the *manufacturer* in the instructions for use.

b) The *ventilator* may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect *basic safety* or *essential performance*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013 applies except as follows:

Addition:

206.101 *Primary operating functions*

a) For a *ventilator*, the following shall be considered *primary operating functions*:

1) setting the *healthcare professional operator*-adjustable controls:

   i) setting *alarm limits*;

   ii) inactivating *alarm signals*;

   iii) switching between different *ventilation-modes* and *inflation-types*; and

   iv) setting ventilation control parameters;

   EXAMPLE 1 *Tidal volume*, *set rate*, *BAP*, pressure support

2) observing and identifying the monitored ventilation parameters;

EXAMPLE 2 *Airway pressure* and expired volume

EXAMPLE 3 FiO_2 (inspiratory oxygen concentration) or $etCO_2$ (end-tidal carbon dioxide concentration)

3) configuring the *VBS* including:

- connection of the detachable parts of the *VBS* to the *ventilator*;

EXAMPLE 4 *Humidifier*, nebuliser[16], water-trap, tubing, *breathing system filter*

4) setting of the adjustable high pressure *alarm limit* to values exceeding 60 hPa (60 cmH_2O);

5) setting of the *airway pressure* to values exceeding 60 hPa (60 cmH_2O);

6) identifying any limitation of the *ventilator's* ability to detect decannulation based on the intended *patient* profile and the *VBS* configuration;

7) connecting or disconnecting the *patient-connection port* of the *VBS* to the *patient*-interface;

8) starting the *ventilator* from power off;

9) turning off the *ventilator*;

10) performing a basic pre-use functional check of the *ventilator* including the *alarm system;* and

11) *processing* the *ventilator* between *patient* uses.

b) The following functions, if available, also shall be considered *primary operating functions*:

1) starting ventilation from standby;

2) activating standby;

3) activating manoeuvres that help assess lung function or the effectiveness of *ventilator* parameter settings;

EXAMPLE 5 *Inspiratory pause*, *expiratory pause*, slow *inflation*

4) activating a closed suctioning function; and

5) attaching the *ventilator* and, where applicable the *VBS*, to a trolley.

c) The following actions associated with ventilation also shall be considered *primary operating functions*:

NOTE For the purposes of this document, the following functions are considered *primary operating functions* even though they might not be performed on the *ventilator's operator-equipment interface.*

1) humidifying/conditioning gases delivered through the *VBS;*

2) adding medication to the gas flowing into the *patient*;

EXAMPLE 6 Nebulisation[16] or injecting fluids into the ancillary port connection of the *VBS*

3) suctioning the *patient's* airway;

4) X-raying the *patient;*

5) providing alternative means of ventilation with a manual resuscitator;

6) positioning the *patient;* and

7) connecting and disconnecting a *distributed alarm system.*

206.102 * Training

In the application of the requirements in 5.6 and 5.8 of IEC 62366-1:2015, training shall be considered necessary for both:

a) the *healthcare professional operator;* and

b) the designee of the *responsible organization* (e.g. *service personnel* or *processing* personnel).

NOTE Requirements for training are found in 5.6 and 5.8 of IEC 62366-1:2015.

Check conformity by inspection of the accompanying document.

208 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems*

IEC 60601-1-8:2006+AMD1:2012 applies except as follows:

Addition:

208.6.3.2.2.2.101 Additional requirements for 1 m (*operator's position*) visual *alarm signals* and *information signals*

High priority alarm signals should be accompanied by information describing possible causes of the *alarm condition* and appropriate actions to take in response. *Operator* action may be required to display this information.

EXAMPLE The obstruction alarm limit has been reached. Check the breathing system tubing for blockages or crimpling. Check breathing system filters for blockage.

208.6.8.3.101 Additional requirements for global indefinite *alarm signal* inactivation states

a) A *ventilator* shall not be equipped with a means to initiate a global *alarm off* while connected to a *patient*.

b) A *ventilator* shall not be equipped with a means to initiate a global *audio off* unless the *ventilator* is connected to a *distributed alarm system.*

Check conformity by functional testing.

208.6.8.4.101 * Additional requirements for termination of *alarm signal* inactivation

The duration of *audio paused* for the *alarm conditions* required by this document shall not exceed 120 s without *healthcare professional operator* intervention.

NOTE This permits a *healthcare professional operator* to deliberately extend the duration of *audio paused* by no more than 120 s following each direct action.

Check conformity by functional testing.

208.6.12.101 * Additional requirements for *alarm system* logging

a) Notwithstanding the requirements of IEC 60601-1-8:2006+AMD1:2012, the *ventilator* shall

   1) be equipped with an *alarm system* log with a capacity of at least 1 000 events in total for:

      i) *high priority alarm conditions*;

      ii) *medium priority alarm conditions;* and

      iii) *alarm signal* inactivation states

2) time stamp all events according to IEC 60601-1-8:2006+AMD1:2012, 6.12 a).

3) not lose the contents of the *alarm system* log during a loss of power for less than 7 d unless deleted by *responsible organization* action.

4) not permit the *healthcare professional operator* to erase the contents of the *alarm system* log.

b) In addition, the *ventilator* should provide a log to include at least the following events:

1) any change of *ventilator* settings, including the value applied;

2) any change of *alarm settings*, including the value applied;

3) change of *patient*, including the *patient* attributes;

4) power supply source change, including the source utilized; and

5) results of the pre-use check.

Check conformity by inspection and functional testing.

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012, Annex C applies, except as follows:

Addition:

201.C.101 Marking on the outside of *ME equipment*, *ME systems* or their parts

Additional requirements for marking on the outside of a *ventilator*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a *ventilator*, its parts or *accessories*

Description of marking	Subclause
Any special storage or handling instructions	201.7.2.101 a) 1)
Any warnings or precautions relevant to the immediate operation of the *ventilator*	201.7.2.101 a) 2)
Containing natural rubber latex, if applicable	201.7.2.13.101 a)
For a *ventilator* intended for the magnetic resonance (MR) environment, MR conditional, if applicable	201.7.2.101 b) 1) ii)
For a *ventilator* intended for the magnetic resonance (MR) environment, MR safe, if applicable	201.7.2.101 b) 1) i)
For *accessories* supplied separately, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.2.4.101 a) 2)
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101 a) 1)
For *accessories* supplied separately, the requirements of 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101	201.7.2.4.101 a) 2)
For each *VBS*, part and *accessory*, contains phthalates, if applicable	201.11.7 cc)
For oxygen inputs, the *rated* range of gas pressure	201.7.2.18 cc)
For packaging of single use or for reusable breathing attachments, containing natural rubber latex, if applicable	201.7.2.17.101 a) 3)
For packaging of single use or for reusable breathing attachments, description of the contents	201.7.2.17.101 a) 1)
For packaging of single use or for reusable breathing attachments, identification reference to the batch, type or serial number	201.7.2.17.101 a) 2)
For the *flow-direction-sensitive components* removable without the use of a *tool*, an arrow indicating the direction of the flow	201.7.2.101 b) 2)
For the *gas output port*, an arrow indicating the direction of the flow	201.7.2.101 a) 3) i)
For the *gas return port*, an arrow indicating the direction of the flow	201.7.2.101 a) 3) ii)
Gas name or chemical symbol	201.7.2.18 aa)
Gas-specific colour coding, if applicable	201.7.2.18 dd)
Indication of the date after which *ME equipment*, part or *accessory* should not be used, if applicable	201.7.2.101 b) 3)
Mandatory action *safety sign*: follow instructions for use	201.7.2.3

Description of marking	Subclause
Rated range of gas pressure	201.7.2.18 bb)
Warning not to obstruct the *gas intake port* , if applicable	201.7.2.101 b) 4)

201.C.102 *Accompanying documents*, general

Additional requirements for general information to be included in the *accompanying documents* of a *ventilator* or its parts are found in Table 201.C.102.

Table 201.C.102 — *Accompanying documents*, general

Description of requirement	Subclause
For each *VBS* and *accessory*, the *model or type reference* of at least one compatible *ventilator*	201.102.2 a)
For each *VBS*, part and *accessory*, a statement to the effect that ventilator breathing systems, their parts and accessories are validated for use with specific ventilators	201.102.2 b) 1)
For each *VBS*, part and *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
For each *VBS*, part and *accessory*, a statement to the effect that the responsible organization is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use	201.102.2 b) 3)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 b)3)i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 b)3)ii)
Means by which the obstruction *alarm condition* is determined	201.12.4.108 g) 1)
Means to test the obstruction *alarm condition*	201.12.4.108 g) 2)
Name or trade name and address of the *manufacturer* and where the *manufacturer* does not have an address within the locale an authorized representative	201.7.9.1
Units of measure for volumes, flows and leakages, for other than the *VBS*	201.7.4.3 aa)
Units of measure for volumes, flows and leakages, for the *VBS*	201.7.4.3 bb)
Ventilator is a high-flow device warning, if applicable	201.4.11.101.2 b)3)iii)

201.C.103 *Accompanying documents*, instructions for use

Additional requirements for information to be included in the instructions for use of a *ventilator* or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Accuracy of expired volume *monitoring equipment, tidal volume* >50 ml	201.12.4.103.1 d)
Accuracy of expired volume *monitoring equipment, tidal volume* ≤50 ml	201.12.4.103.2 b)
Accuracy of the *inspiratory volume monitoring equipment*, if so equipped	201.12.1.104 a)
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.9.2.14.101 b) 2)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101 d)
Any special storage, handling or operating instructions	201.7.9.2.9.101 f)
A-weighted sound power level emitted by the *ventilator*	201.9.6.2.101 b) 2)

Description of requirement	Subclause
A-weighted sound pressure level emitted by the *ventilator*	201.9.6.2.101 a) 2)
Behaviour of the *ventilator* after a switchover to the external reserve electrical power source	201.11.8.101 i) 2)
Behaviour of the *ventilator* after a switchover to the *internal electrical power source*	201.11.8.101 i) 1)
Behaviour of the *ventilator* while the external reserve electrical power source is recharging	201.11.8.101 j) 2)
Behaviour of the *ventilator* while the *internal electrical power source* is recharging	201.11.8.101 j) 1)
Conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101 c)
Cross reference between the *manufacturer*-specific naming of the *ventilator's ventilation-modes* and the *ventilation-mode* systematic coding scheme of ISO 19223	201.7.9.2.9.101 g)
Cross reference to the additional information in the technical description, if the technical description is separable	201.7.9.2.16.101 b)
Description of the algorithm that determines the *alarm limit* values of expired volume *monitoring equipment*, if so equipped	201.12.4.103.1 j) 201.12.4.103.2 g)
Disclosure of any restrictions on the placing of components within the *ventilator breathing system*, if applicable	201.7.9.2.14.101 b) 1)
For a *ventilator* intended for non-invasive ventilation, a warning statement to the effect that the exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask	201.102.7.2 a)
For a *ventilator* intended for non-invasive ventilation, information on how to connect CO_2 *monitoring equipment* to the *VBS* shall be disclosed in the instructions for use unless such equipment is an integral part of the *VBS*	201.102.7.2 b) 2)
For a *ventilator*, an explanation of the meaning of the IP classification marked on the *ME equipment*	201.7.9.2.9.101 d)
For a *ventilator*, its parts or *accessories* intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if the *ventilator*, its parts or *accessories* would be reused	201.7.9.2.1.101 a)
For *accessories* supplied separately where marking the *accessory* is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101 b)
For each *VBS*, part and *accessory*, appropriate precautionary measures for devices that contain phthalates for children or treatment of pregnant or nursing women, if applicable	201.11.6.7 5) cc)ii)
For each *VBS*, part and *accessory*, information on *residual risks* for children or treatment of pregnant or nursing women with devices that contain phthalates	201.11.6.7 5) i)
Indication as to whether the *ventilator* is intended for non-invasive ventilation	201.7.9.2.9.101 e)
Information on how to connect CO_2 *monitoring equipment*, unless such equipment is an integral part of the *ventilator*	201.12.4.104 1) 2)
Information on how to connect O_2 *monitoring equipment*, unless such equipment is an integral part of the *ventilator*	201.12.4.101 6)
Information on how to connect the expired volume *monitoring equipment*, if not so equipped	201.12.4.103.1 0
Intended range of *tidal volume*	201.7.9.2.1.101 b)
Length of time required for the oxygen concentration in the *tidal volume* to change from a volume fraction of 21 % to 90 % of the maximum settable oxygen concentration	201.12.1.105 a)
List of contents of technical description, if the technical description is separable	201.7.9.2.16.101 a)
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value for a *pressure-control inflation* in *normal condition*	201.12.1.102 b) 1)

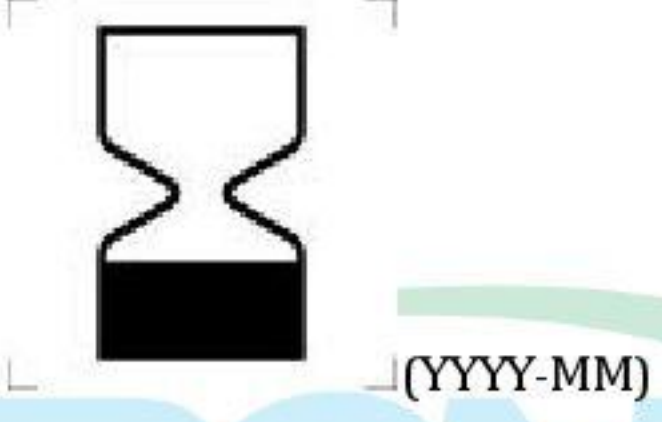
Description of requirement	Subclause
Maximum error of the *inspiratory volume* in relation to the set *tidal volume* for a *volume-control inflation* in *normal condition*	201.12.1.101 b) 1)
Maximum error of the inspiratory oxygen concentration (O_2) at the *patient-connection port* in relation to the set value for a *volume-control inflation* in *normal condition*	201.12.1.101 b) 3)
Maximum error of the inspiratory oxygen concentration (iO_2) at the *patient-connection port* in relation to the set value for a *pressure-control inflation* in *normal condition*	201.12.1.102 b) 3)
Maximum error of the *PEEP* in relation to the set value for *BAP* for a *pressure-control inflation* in *normal condition*	201.12.1.102 b) 2)
Maximum error of the *PEEP* in relation to the set value for *BAP* for a *volume-control inflation* in *normal condition*	201.12.1.101 b) 2)
Maximum limited pressure	201.7.9.2.9.101 a) 1)
Means by which the *maximum working pressure* is accomplished	201.7.9.2.9.101 a) 3)
Means by which the secondary *supply mains* can be tested, if provided	201.11.8.101 h)
Method by which all of the *alarm signals* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 3)
Method by which switchover to and operation from the *internal electrical power source* can be functionally tested to determine if the *ventilator* is operating correctly	201.7.9.2.8.101 a) 2)
Method by which the assembled *VBS* can be functionally tested to determine if it is operating correctly	201.7.9.2.8.101 a) 1)
Operational time of the *ventilator* when powered from a fully charged, aged *internal electrical power source*	201.11.8.101.2 g) 1)
Operational time of the *ventilator* when powered from fully charged, external reserve power source	201.11.8.101.2 g) 2)
Pass-fail criteria for other *inflation-types*	201.12.1.103 a) 2)
Performance of other *inflation-types* in *normal condition*	201.12.1.103 a) 1)
Processing procedure instructions for the *ventilator* and its *accessories*	201.11.6.6 cc) 2)
Rated range of expiratory *gas pathway* resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 1)
Rated range of inspiratory *gas pathway* resistance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 2)
Rated range of *VBS* compliance over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101 b) 3)
Rated range to which the *maximum working pressure* can be set, if adjustable	201.7.9.2.9.101 a) 2)
Recommended *ventilation-mode* and settings for closed suctioning	201.9.101 a)
Statement that *airway pressure* can be subatmospheric during the *expiratory phase* for a *ventilator* that can generate subatmospheric pressure in the *expiratory phase*, if applicable	201.7.9.2.9.101 a) 4)
Statement to the effect that antistatic or electrically conductive hoses or tubing are not to be used in the *ventilator breathing system*	201.7.9.2.14.101 a)
Statement to the effect that the *ventilator* is to be equipped with O_2 *monitoring equipment* for the measurement of inspiratory oxygen concentration before being put into service, if not so equipped	201.12.4.101 a) 1)
Statement to the effect that the *ventilator* is to be equipped with *monitoring equipment* for indicating expired volume at the *patient-connection port* before being put into service, if not so equipped	201.12.4.104 1) 1)
Subatmospheric pressure limit at the *patient-connection port*, for *ventilators* that can generate subatmospheric pressure in the *expiratory phase*	201.7.9.2.9.101 a) 5)

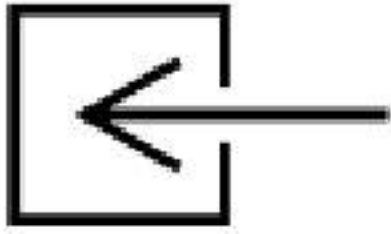
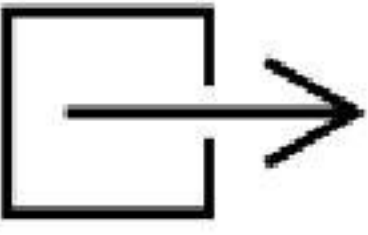
Description of requirement	Subclause
Warning statement to the effect that adding attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory as the ventilator might not function correctly leading to the risk of patient death or serious deterioration of health	201.7.9.2.2.101 c)
Warning statement to the effect that the responsible organization needs to ensure that the oxygen source is compatible with the ventilator	201.7.9.2.2.101 h)
Warning statement to the effect that the *ventilator* accuracy can be affected by the gas added by use of a nebuliser, if applicable	201.7.9.2.2.101 g)
Warning statement to the effect that the ventilator shall not be covered or positioned in such a way that the operation or performance of the ventilator is adversely affected, including applicable examples	201.7.9.2.2.101 a)
Warning statement to the effect that the *ventilator* shall not be used in a hyperbaric chamber, if applicable	201.7.9.2.2.101 d)
Warning statement to the effect that the *ventilator* shall not be used with nitric oxide, if applicable	201.7.9.2.2.101 e)
Warning statement to the effect that the *ventilator* shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium), if applicable	201.7.9.2.2.101 f)
Warning statement to the effect that when using nebulisation or humidification breathings system filters and heat and moisture exchangers can require more frequent replacement	201.7.9.2.2.101 i)
Warning statement to the effect that, in case of *ventilator* failure, the lack of immediate access to appropriate alternative means of ventilation can result in *patient* death or serious deterioration of health	201.7.9.2.2.101 b)
Which portions of the *gas pathways* through the *ventilator* can become contaminated with body fluids or by contaminates carried by expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12 aa)

201.C.104 *Accompanying documents*, technical description

Additional requirements for information to be included in the technical description of a *ventilator* or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document	201.7.9.3.101 a)
Description of which checks are performed automatically for checking the function of the *alarm system* for each of the *alarm conditions* specified in this document	201.7.9.3.101 b)
Disclosure of the essential technical characteristics of each recommended *breathing system filter*, if applicable	201.7.9.3.1.101 d)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3 b)
Pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the instructions for use	201.7.9.3.1.101 b)
Summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means of initiating and terminating the *inflation phase* in each *ventilation-mode* of the *ventilator*	201.7.9.3.1.101 c)

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005+AMD1:2012, Annex D applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1	(YYYY-MM)	IEC 60878:2015[27] Symbol 5.1.4 of ISO 15223-1:2016 ISO 7000-2607	Use by date On packaging. To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging. The expiration date can be a year, year and month, or year, month, day. The date shall be shown adjacent to the symbol. The date may for example be given as follows: 1997-06-12. The date shall be expressed as in ISO 8601:2019[28] as four digits for the year and, where appropriate, two digits for the month and two digits for the day. For some medical devices (e.g. IVDs), this date is only valid when the medical device is unopened.
2	STERILE	IEC 60878:2015[27] Symbol 5.2.1 of ISO 15223-1:2016 ISO 7000-2499	Sterile On medical devices or its packages. To indicate that the device is provided sterile. Indicates a medical device that has been subjected to a *sterilization process*. NOTE Use of this symbol precludes the use of symbols 2500, 2501, 2502 or 2503.
3	STERILE A	IEC 60878:2015[27] Symbol 5.2.2 of ISO 15223-1:2016 ISO 7000-2500	Sterilized using aseptic *processing* techniques On medical devices or its packages. To indicate that the device is provided sterile and has been sterilized using aseptic *processing* techniques. Indicates a medical device that has been manufactured using accepted aseptic techniques. NOTE 1 Aseptic techniques can include filtration. NOTE 2 Use of this symbol precludes the use of symbol 2499.

No	Symbol	Reference	Title and description
4	STERILE EO	IEC 60878:2015[27] Symbol 5.2.3 of ISO 15223-1:2016 ISO 7000-2501	Sterilized using ethylene oxide On medical devices or its packages. To indicate that the device is provided sterile and has been sterilized using ethylene oxide. Indicates a medical device that has been sterilized using ethylene oxide. NOTE Use of this symbol precludes the use of symbol 2499.
5	STERILE R	IEC 60878:2015[27] Symbol 5.2.4 of ISO 15223-1:2016 ISO 7000-2502	Sterilized using irradiation On medical devices or its packages. To indicate that the device is provided sterile and has been sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation. NOTE 1 This symbol can be used to indicate that the product has been subjected to irradiation *processes*. NOTE 2 Use of this symbol precludes the use of symbol 2499.
6	STERILE	IEC 60878:2015[27] Symbol 5.2.5 of ISO 15223-1:2016 ISO 7000-2503	Sterilized using steam or dry heat On medical devices or its packages. To indicate that the device is provided sterile and has been sterilized using steam or dry heat. Indicates a medical device that has been sterilized using steam or dry heat. NOTE Use of this symbol precludes the use of symbol 2499.
7	LOT	IEC 60878:2015[27] Symbol 5.1.5 of ISO 15223-1:2016 ISO 7000-2492	Batch code To identify the *manufacturer's* batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
8	REF	IEC 60878:2015[27] Symbol 5.1.6 of ISO 15223-1:2016 ISO 7000-2493	Catalogue number To identify the *manufacturer's* catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
9	SN	IEC 60878:2015[27] Symbol 5.1.7 of ISO 15223-1:2016 ISO 7000-2498	Serial number To identify the *manufacturer's* serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
10	LATEX	IEC 60878:2015[27] Symbol 5.4.5 of ISO 15223-1:2016 ISO 7000-2725	Presence of, contains, [natural rubber latex] On medical devices: to indicate that the equipment contains the identified product or substance.

No	Symbol	Reference	Title and description
11		IEC 60878:2015[27] ISO 7000-0794	Input; entrance To identify an entrance, for example exhaust gas entry for measurement (for example of CO- value). For electrical (signal) input use symbol IEC 60417-5034.
12		IEC 60878:2015[27] ISO 7000-0795	Output; exit To identify an exit, for example of a hydraulic pump. For electrical (signal) output use symbol IEC 60417-5035.
13	XXX	IEC 60878:2015[27] ISO 7000-2725 EN 15986:2011	Contains or presence of [XXX] On medical devices: to indicate that the equipment contains the identified product or substance. Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.
14	MR	IEC 60878:2015[27] Symbol 7.3.1-1 of IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
15	MR	IEC 60878:2015[27] Symbol 7.3.1-2 of IEC 62570:2014	MR Safe Alternative graphical symbol representation. Same meaning as IEC 62570-7.3.1-1.
16	MR	IEC 60878:2015[27] Symbol 7.3.2 of IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. The MR Conditional symbol may be supplemented by supplementary marking that describes the conditions for which the item has been demonstrated to be MR Conditional.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document.

Subclause 201.1.1 — Scope

ISO 80601-2-12 *ventilators* are not considered a *physiologic closed-loop control system* due to the fact that parameters monitored during delivery of respiratory gases that are also used to control the delivery of these gases are exclusively physical parameters of the delivered gases. Consequently, these parameters are considered equipment variables as specified in IEC 60601-1-10.

A *pressure-control ventilator* that uses the breathing system pressure as a feedback to control breathing system pressure is a closed-loop control system, but not a *physiologic closed-loop control system*. The breathing system pressure is considered both a 'variable' influenced by the *patient* physical conditions and at the same time a 'feedback variable', but it is not a quantity or condition measured from the *patient's* physiology.

The *patient* by its physical condition is a disturbance on the closed loop system but the *ventilator* does not adjust the ventilation therapy settings based on measurement of these *patient* parameters.

The requirements of this document do not require the *ventilator* to adjust ventilation delivery parameters based on the detection in the change of physiological conditions of the *patient*. All automatic adjustments of *ventilator* equipment parameters or generated *alarm conditions* are only based on the measurement of physical variables related to the delivery of breathing gas to the *patient-connection port*. In this sense the *ventilator* ends at the *patient-connection port*, (i.e. has no direct contact to the physiological parameters of the *patient*) and a change in the *patient's* physiological conditions is a disturbance to the *ventilator's* control system that does not act to control the physiological change but continues to control the physical variable(s) to their original objectives.

Ventilators create *alarm conditions* when detecting faults in the delivery of breathing gases to the *patient-connection port* but do not adjust therapy setting of the *ventilator*.

The following are examples of medical devices that are considered *physiologic closed-loop control system*.

— Insulin infusion pump that adjust the rate of insulin infusion to the *patient* based on the measurement of blood glucose. The physiological feedback mechanism is a blood glucose level monitored by the device.

— External pacemaker that adjusts the pace rate based on the measurement of the cardiac output value. The physiological feedback mechanism is the value detected by the cardiac output monitor.

Unlike a *ventilator*, these devices titrate delivery to the *patient* based on the measured physiological parameter. A *ventilator* will not titrate but will either stop ventilation or generate an *alarm condition*.

Definition 201.3.209 — *Professional healthcare facility*

Unlike the *home healthcare environment*, the environment in a *professional healthcare facility* is considered to be a controlled environment. That is, *supply mains* is reliable with minimum variations and sometimes with backup power. The protective earth connection is robust. Temperature, humidity and altitude conditions are stable, and disruptions from electromagnetic disturbances are controlled.

Subclause 201.4.3.101 — Additional requirements for *essential performance*

The modern critical care *ventilator* with an active exhalation valve has differing *ventilation-modes* that can consist of multiple *inflation-types*. This is necessary as *patient* response to ventilation is unpredictable. *Patient*-initiated breaths or *inflation*s where the inspiration is terminated by the *patient* can have characteristics that are different from those that have been set by the *healthcare professional operator*. *Essential performance* as "ventilation within the *alarm limits* set by the *healthcare professional operator*" is inclusive of those *inflation*s that the *patient* modifies outside of the ventilatory parameters set by the *healthcare professional operator*, but still within the *alarm limits* which are considered safe by the *healthcare professional operator*.

It is expected that the *healthcare professional operator* will set appropriate *alarm limits* which thereby define the *essential performance* for a particular *patient*.

The distributed *essential performance* criteria captured in Table 201.101 have been identified by the committees as the minimum clinical performance necessary to reduce the probability of exposing the *patient* to unacceptable *risk*. Conformance criteria for some of the clauses within IEC 60601-1, this document and the other applicable collateral standards include "maintain *essential performance*". The committees have recognized the difficulty in confirming that all aspects of *essential performance* are maintained when completing longer duration testing.

Footnote a to Table 201.101 indicates methods of evaluating delivery of ventilation as acceptance criteria following specific tests required by this document. It is intended to provide criteria that can be used to easily confirm that *essential performance* has been maintained. Although the degradations detailed in 202.8.1.101 are associated with *immunity* testing, the same criteria are intended to be used when the conformance criteria from any other clause or subclause require confirmation that *essential performance* is or has been maintained.

Those aspects of *essential performance* that cannot be reasonably linked to the conformance criteria within 202.8.1.101 need to be confirmed via other means. However, one need only

confirm that the specific requirements indicated in 202.8.1.101 that are likely to have an impact on specific clinical performance are maintained after testing.

Subclause 201.4.6 — *ME equipment* or *ME system* parts that contact the *patient*

Since much of the *VBS* is likely to be draped over or around the *patient*, it is likely to come into direct contact with the *patient* during *normal use*. Also of concern are electrical *hazards* should any circuitry be incorporated into the *VBS*. By ensuring that the *gas pathways* of the *VBS* and its parts or *accessories* are subject to the requirements for *applied parts*, these issues are addressed by the requirements already in the general standard.

Subclause 201.4.11.101 — Additional requirements for pressurized gas input

A critical care *ventilator* designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures, but these pressures can only be maintained if the *ventilator* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that a *ventilator* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurized gas supply.

Pressurized medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant standards, supply medical gasses to gas-specific terminal outlets at a pressure that is within an internationally agreed-upon pressure range of 280 kPa to 600 kPa under *normal condition*. It is expected that critical care *ventilators* should operate to their declared specification with any supply pressure within this range.

In the case of a pressure regulator failure the gas supply pressure could rise to the pressure regulator's supply pressure – which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered *ME equipment* should be designed so as not to present an unacceptable *risk* if its supply pressure rises up to this value but in the case of critical care *ventilators* it is considered that, because all the *ventilators* in a critical care unit could be affected simultaneously, it is not acceptable that such *ventilators* should just generate an *alarm signal* and shut down under these overpressure conditions. For this reason, there is a specific requirement that *ventilators* should continue operation with acceptable performance so that *patients* can continue to be ventilated until such time as normal operation can be restored or that alternative means of ventilation can be used.

Ventilators with maximum *rated* input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum *rated* input pressure.

Under the *single fault condition* that the supply pressure of any one gas drops below 280 kPa, under steady-state conditions, it is understood that a *ventilator* cannot be expected to continue to operate on this gas. However, it is required that in this case the *ventilator* should detect the unacceptable low pressure, produce an *alarm signal* and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the *ventilator*. This requirement is stated in 201.13.2.102.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems* supplying compressed medical gases through gas-specific terminal outlets are designed so that they can maintain this pressure at the input of gas-powered devices whilst supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline. Account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop across the terminal unit and the hose assembly connecting the device to the pipeline at 60 l/min.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a 'diversity factor'; a factor agreed between the supplier and *responsible organization* to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flowrate of 60 l/min to the required proportion of terminal outlets. However, if the flowrate demand from many adjacent *ventilators* exceeds 60 l/min there is an increased possibility that the *ventilator* input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a *patient* demand system can result in a *ventilator* requiring transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize pressure drop, such transient demands can generally be accommodated from the gas stored locally within the pipe work of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the inlet of the *ventilator* to below 280 kPa, due to transient flows in excess of 200 l/min (over 3 s), but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their *ventilators* when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulators conforming to ISO 10524-1:2018[29].

Ventilators that can draw greater average or transient flows during *intended use* are permitted, but their *accompanying documents* are required to disclose those flows and warn of the need for a different diversity factor.

The average flowrate of 60 l/min is greater than the test flowrate used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The committee responsible for *medical gas pipeline systems* standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flowrate value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of standards for *medical gas pipeline systems* and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other standards for supply systems for medical gases permit the fitting of gas-specific terminal outlets to spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101.2 — Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally, one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~37 °C) irrespective of the temperature of the gas delivered by a *ventilator*. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including *ventilators*, follow engineering conventions and specify gas quantities and flowrates at *STPD* conditions. This practice is followed in this document for all requirements concerning gas input.

However, *ventilators* conforming with this document are likely to be inflating the *patient's* lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from a *ventilator*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* (*standard temperature pressure dry*) can expand the lungs to 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *ventilators*, it is essential that the information for all *ventilators* is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, *BTPS* is the appropriate set of reference conditions to use.

In *ventilators* a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

The necessary corrections also depend on the location of the flow transducer in the *VBS*. The humidity of the gas can be zero when the transducer measures the inspired flow inside the *ventilator*. When, however, the flow transducer is located at the Y-piece, the relative humidity can be anything up to 100 %. When a *heat and moisture exchanger* is used for humidification, the output of the flow transducer depends on whether it is located distal or proximal to the *heat and moisture exchanger*. With a blower- or compressor-based *ventilator* that uses ambient air, the humidity of the drawn-in air can be unknown to the *ventilator*. All these effects together will inevitably introduce some errors in the conversion of the measured flow signal to *BTPS* reference conditions. However, these errors are only in the range of several percent. For *tidal volumes* greater than 50 ml, the committee came to the conclusion that the permitted inaccuracy of the measurement of ±(4 +(15 %)) ml is sufficiently wide and includes the inaccuracy of the flow transducer and the inaccuracy of the conversion to *BTPS* conditions. However, it remains the responsibility of the *manufacturer* to verify that the accuracy requirements of 201.12.1 and 201.12.4.103 are met.

Subclause 201.5.101.3 — *Ventilator* testing errors

When testing *ventilator* performance, several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognize the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 %, then the test acceptance criterion is ±7 %. If a third party is testing to this document, they also need to include measurement uncertainty in their testing. If they subsequently obtain an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.2.3 — Consult *accompanying documents*

The committee agreed that following the instructions for use is a mandatory action for the safe operation of a *ventilator*.

Subclause 201.7.2.101 — Additional requirements for marking on the outside of *ME equipment* or *ME equipment* parts

Essential principle, 21.5, of ISO 16142-1:2016 and the European Medical Devices Regulation 2017/745 General Safety and Performance Requirement, 23.2, places requirements on the *manufacturer* of a medical device to include information on the medical device or *accessory* label that includes “any special storage and/or handling conditions” and "any special operating instructions". These requirements provide information to the *operators* of the medical device intended to ensure that it is stored and handled in a manner that does not adversely affect medical device performance or safety.

It is not expected that this would include storage conditions common to most similar medical devices, such as a storage temperature range (unless this is more restrictive than the operational temperature range). This subclause requires labelling for information that is necessary to prevent a *hazard*, and that might not be evident to *operators* of other medical devices.

One example would be for a medical device with an internal battery that is required to be functional even when connected to the *supply mains* (for example to provide for surge current for a medical device with a very variable power consumption or to maintain a real-time clock during periods of storage). For this medical device it would be appropriate to include labelling to leave the *ventilator* connected to wall power when not in use; the *operator* of the equipment cannot be assumed to recognize that such equipment with an internal battery might nonetheless become unusable even when connected to wall power if the battery is left to discharge while not in use.

A further example would be for a medical device with an internal fluid reservoir, which could leak externally, or cause a component failure, if the medical device were to be stored upside down. It is very common for *ME equipment* to be stored in orientation that is distinct from the operating position, so for this medical device it would be appropriate to include labelling to show permissible orientation.

Subclause 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

a)

A cover (e.g. a curtain or an unfavourable position of the *ventilator*) could cause the air inlets or openings of the *enclosure* to be partly or fully blocked. Air inlets are inlets for ambient air for blower-driven *ventilators* or *emergency intake ports*.

Openings in the *ventilator* housing are required for circulation of air for cooling and removal of leaked medical gases of the *ventilator*.

b)

In case of a severe *ventilator* failure, the *ventilator* stops ventilating the *patient*. There is no back-up mechanism for an alternative means of ventilation integrated in the *ventilator*; a *ventilator* is not required to be functional under *single fault condition*. To keep the time for a possible interruption of the ventilation of the *patient* as short as possible, an alternative means of ventilation has always to be available close to the *ventilator*.

c)

Additional attachments or other components or subassemblies increase the resistance and compliance of the *VBS*. The additional flow of a pneumatic nebuliser[16] or the sampling flow of a diverting gas monitor could have a negative impact on the accuracy of the measurement of the flowrates and oxygen concentration.

d)

Components of critical care *ventilators* are typically not designed for the high ambient pressures in a hyperbaric chamber (e.g. 2 000 hPa). Ambient pressure sensors might not be calibrated for high ambient pressures resulting in severe failure of the *ventilator*. The high ambient pressure also can cause an incorrect measurement of the flowrate and oxygen concentration.

The much higher partial pressure of oxygen in a hyperbaric chamber would increase the *risk* of fire in the *ventilator*. A *ventilator* intended for use in a hyperbaric chamber requires special design considerations beyond the requirements of this document.

e)

Nitric oxide can cause significant material compatibility issues with the components of some *VBS* (e.g. flow sensors).

f)

Helium and gas mixtures with helium have characteristics that are significantly different from those of air or air-oxygen mixtures. This decreases the accuracy of the flowrate measurement and impairs the ventilation function.

Because of the changed oxygen concentration caused by helium or mixtures of helium the delivered oxygen concentration for the *patient* would be incorrect. *False positive alarm conditions* for both level and low oxygen concentrations can result.

Because of the very low density of helium, the gas leakage in the *VBS* is also increased. The low density also has an impact on the measurement of the resistance in the *VBS*.

g)

The additional gas flow in gas volume reduces the accuracy of the flowrate measurement with a subsequent impairment of the ventilation function.

h)

Ventilators need for their proper function a specific range of pressure, flowrate and gas concentration at the *high-pressure input ports*. Deviations of the inlet gas concentration for oxygen can influence the calibration of the oxygen sensor. Significant inaccuracies of the measurement of inspiratory oxygen concentration can occur.

In case the pressure or the deliverable flow of the central gas supply is too low, the *ventilator* would switch over to the remaining gas, e.g. from oxygen to air, with impact on the delivered oxygen concentration.

i)

The functionality of *breathing system filters* is affected by a number of aspects of structure, properties and local environment.

At the most basic, a *BSF* is designed to be a filter that removes particles suspended in gas, i.e. a "dry aerosol". The particles primarily targeted in the *VBS* are bacteria or virus particles (although other particles would be subject to retention). The filtering material ("medium") is composed of a matrix of solid material with open passageways to allow gas flow. The passageways in such gas filters are relatively large compared to the bacteria and virus particles that are to be removed. The spatial arrangement of the solid part of the filter medium versus the open spaces in the medium brings the particles in proximity to the surfaces of the medium, where physical forces (electrostatic attraction and Van der Waals forces) attract and bind the particles within the matrix, removing them from the gas flow.

In the practical situation of anaesthesia or respiratory care therapy, environmental factors related to the *patient*, or the therapy can alter the performance of the *BSF* from that which would occur in the simple flow of air with suspended microorganisms though the *BSF*.

One major factor is the presence, phase, and amount of moisture present in the airflow.

When there is low humidity in the air (gaseous phase moisture) the gaseous water molecules will generally pass though the filter medium without effect. If there is a sufficiently high relative humidity, some *BSFs* can adsorb or absorb part of this humidity.

If the moisture exists as a liquid aerosol, the water droplets can also be retained by the filter.

The properties of a filter medium that govern the degree to which this interaction with water takes place is its relative affinity for water. A medium which readily attracts water is termed "hydrophilic" and a medium which repels water is termed "hydrophobic". These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

Another example of liquid phase water can be termed "bulk water". An example of this is the collected condensate that occurs in the expiratory limb of the *VBS*. Depending on the management of the circuit, and the positioning of the *BSF*, this bulk water can actually completely cover and occlude the filter. If a sufficient pressure is applied, the liquid water can be forced though the pores of the filter medium. This requires relatively low pressure for a hydrophilic filter and relatively high pressure for a hydrophobic filter.

The practical consequences of the latter scenario is that if liquid is forced though a hydrophilic *BSF*, gas flow blockage can be relieved, but any microorganisms removed by the filter can be carried past the filter with the liquid stream. In the case of a hydrophobic filter, the pressure in the *VBS* is usually not sufficient to force liquid though the medium, so the microbial retention is not compromised. Airflow occlusion persists, however, until steps are taking to remove the bulk water.

In addition, there can be a temporal aspect to the properties of relative hydrophilicity or hydrophobicity; whereby prolonged exposure to water alters these properties during the *expected service life* of the *BSF*. A *BSF* is typically labelled with an *expected service life*, in hours or days, that reflects its ability to perform to its labelled specifications in the clinical environment.

It should be obvious that the potential influence of water on performance differs in anaesthesia and respiratory care applications, although many, if not most, *BSFs* are indicated for use in both applications.

Additional effects on *BSF* functionality can be caused by the introduction of substances other than water or gas into the device. Such substances can originate from the *patient* (e.g. sputum, exudates, blood, vomitus) or substances introduced by the *operator* into the *VBS* (e.g. gross amounts of medications intended to be nebulised[16] for administration though the *VBS*).

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at *ventilator* or physiologic pressures. In the case of nebulised medications, the type of nebuliser[16], and its operating parameters are variables that affect the likelihood or magnitude of significantly increased *BSF* flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during *operator* or *patient* manipulation of the *VBS* has been implicated as a source of acute *BSF* blockage.

The cause of increased flow resistance in a *BSF* can be gross blockage of the medium passages, or the effects of surfactant properties of the substances introduced into the *BSF* upon the hydrophobicity of the filter medium. It should be noted that medications indicated for nebulisation can contain surfactant materials that are not identified in the medications' labelling with respect to their presence or their quantity, and these can change without notice for a given medication. The effect of these substances upon flow resistance differs among individual models and brands of *BSFs*.

The *operator* needs to be aware that the effects of such substances can be manifested as increases in the amount of positive *airway pressure* required for a *ventilator*-provided breath, or as an increase in expiratory flow resistance, resulting in a step-wise increase in intrapulmonary pressure that, if not detected, can lead to pneumothorax.

Awareness of the possibility, albeit infrequent or rare, of such significant increases in *BSF* flow resistance, and inclusion in a trouble-shooting scheme for this and other causes of impaired ventilation can reduce or eliminate adverse events occurring secondary to *BSF* flow occlusion.

Direct *patient* monitoring, and usage of the appropriate settings for, and prompt attention to, *ventilator alarm conditions* are essential to provide maximum *patient* safety.

Once a *BSF* is recognized to be a source of impaired ventilation, simply removing the occluded *BSF* and replacing it with another *BSF* returns ventilation to a normal state.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up *procedure*

In some designs, adequate checking of the *alarm system* can be performed with a combination of *operator* action and the power-on self-test routines that verify the integrity of the software and the computer controlling the *ventilator*, as well the measuring sensors and the *alarm signal* generation.

Subclause 201.7.9.2.9.101 — Additional requirements for operating instructions

b)

Some *ventilators* are designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. This can be required to provide the greater length needed during MRI *procedures*, for example. Thus, knowledge of these *VBS* characteristics is important for the *healthcare professional operator* to be aware of the *ventilator* capability. Also, knowledge of the maximum *VBS* resistance (at *nominal* and maximum flowrates) is important because an occlusion *false positive alarm condition* can be caused by the use of high-resistance components in the *VBS*. These characteristics of the *VBS* need to be inclusive of any inhalation or exhalation particle/*BSF*, *humidifier*, nebuliser[16], water collection vessels and connectors needed for operation.

Subclause 201.7.9.2.14.101 — Additional requirements for *accessories*, supplementary equipment, used material

The use of antistatic or electrically conductive materials in the *VBS* is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the *risk* of electrical shock to the *patient*.

Subclause 201.7.9.2.16.101 — Additional requirements for reference to the technical description

Instructions for use are often kept as simple as possible so that the *healthcare professional operator* can easily find and follow important information. Therefore, more technical information, such as required by this subclause, is better placed in the technical description. However, without adequate cross-referencing, a *healthcare professional operator* facing a problem might not be aware that additional information is readily available in a separate document.

Subclause 201.7.9.3.1.101 — Additional general requirements

a)

The *manufacturer* is expected to express the description of the *ventilator* in general terms so the reader can understand the important behaviour of the *ventilator*, e.g. mean values and their time specifications, number of *inflations* and delays, etc.

Subclause 201.9.6.2.1.101 — Additional requirements for audible acoustic energy

Table 201.101 — Test conditions for acoustic tests

After due consideration, the committee decided that where this document specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end value of both ranges should be applicable to both ranges. This means that a *manufacturer* is free to use a

round number end value (e.g. 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to satisfy also the test requirements of the adjacent range. This permits, for example, one *ventilator* to have a declared *tidal volume* range of 300 ml to 1 000 ml and another 100 ml to 300 ml, with each *ventilator* only being required to be tested for the conditions specified for ≥300 ml or ≤300 ml respectively.

Subclause 201.9.101 — Additional requirements for suction *procedures*

It is now common practice in critical care areas to use a closed *suction catheter* during artificial ventilation of a *patient*. Use of a closed *suction catheter* allows uninterrupted artificial ventilation without disconnection of the *VBS* from the tracheal tube, tracheostomy tube or other airway device. This is in contrast to the use of a traditional open *suction catheter* which requires the opening or disconnection of the *VBS* before application of subatmospheric pressure to the respiratory tract.

A closed *suction catheter* is provided with an adaptor that permits its connection at the *patient-connection port*. When used as intended, an in-line or closed *suction catheter* and related suction equipment become an *accessory* to the *ventilator* and an extension of the *VBS*. When a *VBS* is equipped with a *suction catheter* adaptor, the *patient* end of the closed *suction catheter* adaptor becomes the 'new' *patient-connection port*.

While use of closed *suction catheters* is regarded as expected *normal use* by a *healthcare professional operator*, the related subatmospheric pressures within the *VBS* have been known to damage some *ventilators*[30][31].

The purpose of this requirement and test method is to replicate these worst-case in-use conditions caused by a closed *suction catheter* and to demonstrate that a *ventilator* resumes intended function after (but not during) the use of a *suction catheter*.

Subclause 201.11.1.2.2 — *Applied parts* not intended to supply heat to a *patient*

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without *harm* to the respiratory tract[32]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract[33]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (256 kJ/kg) for 45 min[34].

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,978 6 m^3/kg of dry air and an enthalpy content of 197 kJ/m^3 of dry air. Assuming the volume breathed by the *patient* is the same whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/m^3 of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the *patient*.

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a *ventilator* in clinical practice, the delivered gas energy limit of 197 kJ/m^3 of dry gas when averaged over 120 s can be used. This allows a safety margin of approximately 25 % relative to the enthalpy figure of 197 kJ/m^3 confirmed to be safe[33].

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the *patient* with a normal body temperature of 37 °C. Dry gas at body

temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 181,3 kJ/m³ of dry gas breathed by the *patient*.

The enthalpy content of 197 kJ/m³ has for a long time been in use to limit the energy transfer of humidified breathing air to the respiratory tract of a *patient* with bypassed upper airways and no negative feedback with regard to this limitation was known at the time of the consideration of this document. Even in the vulnerable neonatal *patient* population, the committees are aware of no reports of injury resulting from excessive thermal output from a respiratory gas *humidifier* when operating to specification. The committees asked for clinical advice as to whether in addition to the enthalpy limitation, the temperature needed also to be limited. A German group of clinicians, after considering the issue and the literature available, came to the following conclusion:

> The literature shows[32][33][34]:
>
> — thermal inhalational traumas with temperatures above 100 °C but with unknown humidity content;
>
> — the very low RH of about 5 % only at 100 °C with an enthalpy content of 197 kJ/m³;
>
> — the good experience with the limit of enthalpy content of 197 kJ/m³ of dry air in humidified breathing gases;
>
> — the physical facts that a blower/turbine type *ventilator* increases the temperature of the gas taken from the environment in the range of 15 °C to 25 °C;
>
> — *ventilators* are used in environments up to 45 °C;
>
> — an additional temperature limitation is intended to limit the temperature under worst-case condition; and
>
> — a sufficient safety margin to protect the *patient* from thermal injuries of its airways.
>
> The clinician group recommended to keep the thermal energy limitation of 197 kJ/m³ and add a maximum temperature limitation of 70 °C, whichever is lower. The committees agreed and confirmed this proposal.

Subclause 201.11.6.5.101 — Additional requirements for ingress of water or particulate matter into *ME equipment* or *ME system*

Critical care *ventilators* are life-sustaining. Fluids commonly found in the critical care environment include saline, blood and other body fluids.

The committee agreed that the IP22 designation provided the most appropriate requirements to ensure that the *ventilator*, its *accessories* and parts maintain *basic safety* and *essential performance* during *normal use*.

Subclause 201.11.6.6 — *Cleaning* and *disinfection* of *ME equipment* or *ME system*

The *essential principles* of ISO 16142-1 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the *patient* on whom they are being used or the employees or third parties interacting with them.

This means that *ventilators*, their *accessories* and parts cannot be used if there is an unacceptable *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *ventilator*, *accessory* or part.

Therefore prior to reuse, *ventilators*, their *accessories* and parts require an appropriate level of *disinfection*, depending on their use, but rarely need to be sterile.

Recommendations for hygienic *processing* of *ventilators*, their *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* in this document are intended to:

— make the *responsible organization* for *processing* the *ventilator* aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the *processing* of *ventilators*, their *accessories* and parts to conform with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regard to implementing the hygiene measures required for the *patient's* safety.

The *manufacturer* is encouraged to concentrate on four essential aspects of *cleaning* and *disinfection*:

a) the external *enclosure* of the *ventilator;*

b) the *ventilator's* removable breathing circuit, including *accessories* and parts (e.g. *humidifier*, removable flow sensor, connectors, water traps, *breathing system filters*);

c) the internal *gas pathways* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition*, which generally reside within the *ventilator's enclosure* and are normally replaced or processed between *patients;* and

d) the internal *gas pathways* that cannot become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition*, which generally reside within the *ventilator's enclosure* and are not normally removed or processed between *patients*.

Regarding the *cleaning* and *disinfection* or *cleaning* and *sterilization* of a), b) and c), above, *manufacturers* are required to provide detailed *validated procedures* for ensuring safe and effective *processing* to protect the next *patient*, caregivers, technicians and third parties from pathogenic contamination. *Manufacturers* are required to document these *procedures* in the *accompanying documents* of the *ventilator*. Since the *gas pathways* described in d) above are not contaminated by a *patient*, *manufacturers* are not required to provide, *validated procedures* for *processing* them. Item c) and to some extent item d), the *disinfection* of the *ventilator's* internal *gas pathways*, have received renewed attention due the recent outbreaks of contagious diseases like Legionnaires', SARS (severe acute respiratory syndrome) and influenza that affect the respiratory system.

Most modern *ventilators* are designed to permit removal, either for replacement or *processing*, of those portions of the internal *gas pathways* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition*. *Responsible organizations* need to follow their infection control *procedures* when transferring a *ventilator* from one *patient* to another.

In the event that the *responsible organization* suspects that the internal *gas pathways* of a given *ventilator* might have become contaminated with pathogenic material from the previous *patient*, the committee suggests a three-step *process* in the following order to assess next actions:

— ensure that the breathing circuit and all *accessories* have been removed and dealt with according to applicable *procedures;*

— thoroughly disinfect all outer surfaces of the *ventilator enclosure*, including the outer surfaces of the *gas output port* and *gas return port;* and

— only after executing the previous two steps, swab the inner surfaces of the *gas output port* and *gas return port* and culture the swabs to determine if pathogenic material is present.

If contagious pathogens are detected, the *responsible organization* should follow the *manufacturer's processing procedures* found in the *accompanying documents* to protect the next *patient*, caregivers, technicians and third parties from those detected pathogens. The *responsible organization* should be aware that sensitive and expensive sensors are likely to be located in the expiratory *gas pathways*. Follow the *accompanying documents* of the affected *ventilators* to ensure that delicate and possibly fragile sensors are not damaged during the *processing procedure*.

Any *ventilator* that has already been used on another *patient* could be contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the device or the next *patient* on whom the device is used. Hence the *gas pathways* of *ventilators*, their reusable *accessories* and parts that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* and have been used should, when required for appropriate infection control, undergo a *processing procedure* following the *manufacturer's* instructions, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of a *ventilator*, its *accessories* or parts:

— protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing procedure*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles); and

— the necessity to guarantee that standardised *procedures* have consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedure* should be determined by:

— the potential degree and type of contamination of the *ventilator*, *accessories* or parts; and

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *ventilator*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* rebreathing under *single fault condition* is required.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail so that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if the:

— documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*; and

— reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the *ventilator*, *accessories* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator* or other persons; and

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by a processed *ventilator*, *accessories* or parts are determined by the following factors:

e) undesired effects, which can result from:

  — the previous use,

  — the previous *processing procedures*, and

  — transportation and storage;

f) the *risks* from subsequent uses, such as the following:

  — residues from the previous use (such as secretions, other body fluids, and drugs);

  — residues from the previous *processing procedures* such as *cleaning* agents, disinfectants and other substances, including their reaction products;

  — changes of physical, chemical or functional properties of the device; and

  — changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

g) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing procedure* and the feasibility of the *processing procedure* for the *ventilator*, *accessories* or parts, the *manufacturer* should consider the following points:

— the *risks* involved in the *processing procedure*;

— the cost effectiveness of the *processing procedure*;

— the practicability of the *processing procedure*;

— the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing procedure*;

— the efficiency of the *processing procedure*;

— the reproducibility of the *processing procedure*;

— quality management requirements of the *processing procedure*; and

— the environmental impact of the *processing procedure* and the disposal of the *ventilator*, *accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *ventilator*, *accessories* or parts, depending on the type of use.

The *responsible organization* should verify that *cleaning* and *disinfection* of the *ventilator*, *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants, and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected *ventilator*, *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact, either directly or indirectly, with the next *patient*, *operator* or another person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, a safety and functional testing of the *ventilator* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *ventilator*.

The extent and type of the tests depends on the *ventilator*, *accessory* or part and these need to be defined in the *accompanying document*.

Subclause 201.11.8.101 — Additional requirements for interruption of the power supply/*supply mains* to *ME equipment*

The operating time of a battery depends significantly on the number of charging and discharging cycles. Therefore, the committees decided that the *manufacturer* has to disclose the operating time in the instructions for use with both fresh and with aged batteries.

For aging a battery, the number of charging and discharging cycles was defined by the committees as 10 cycles for a *stationary ventilator* and an additional 40 cycles for a *transit-operable ventilator*, which means in total 50 cycles.

The assumption for the 10 cycles for a *stationary ventilator* was that every month there would typically be a single power breakdown in the hospital.

The assumption for the 50 cycles for a *transit-operable ventilator* was that 40 times per year the *ventilator* would be used for *patient* transport within the hospital and that every month there would typically be a single power breakdown in the hospital.

Subclause 201.12.1 — Accuracy of controls and instruments

The committee considered that the accuracy of set and displayed values is a key component of the *essential performance* of a *ventilator* (i.e., the delivery of ventilation at the *patient-connection port* within the *alarm limits* set by the *healthcare professional operator* or generation of an *alarm condition)*. The general standard requires *manufacturers* to declare accuracies and to address the associated *risks* in the *risk management process*. One of the associated *risks* is lack of consistency between *manufacturers* in their declarations of accuracy, both in terms of the reference settings used and the conditions of testing. Consistency in these situations can only be achieved by means of internationally agreed standards and these requirements have been formulated in order to fulfil this objective.

The test settings and conditions and, for certain parameters, minimum requirements, specified in this subclause have been selected by the committee as those necessary to demonstrate adequate *essential performance* of a critical care *ventilator* with regard to the parameters specified. The test *procedures* have been written as *type tests* (additional information is found in 3.135 and Clause 5 of the general standard), with the expectation that *manufacturers* will design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified will encompass any results obtained by a *type test* performed in accordance with the test *procedures* specified in this subclause.

Subclause 201.12.1.101 – *Volume-control inflation-type*

b) 3)

A *ventilator* that is intended for use with a *medical gas pipeline system* driven from Oxygen 93 (from an oxygen concentrator) requires a wider *rated* range of input oxygen concentration than a *ventilator* intended only for use with a *medical gas pipeline system* driven from oxygen. For a *ventilator* intended for use only with oxygen, the *rated* range of concentration for the oxygen inlet would typically be "99,5 % ± 0,5 %" (or alternatively "99,0 % to 100,0 %"). For a *ventilator* intended for use with a *medical gas pipeline system* driven by Oxygen 93, the *rated* concentration could be as wide as "90 % to 100 % O_2" where the *medical gas pipeline system* is backed up with oxygen. The *manufacturer* is required to disclose the effects of variation in the inlet oxygen concentration within the *rated* range on delivered oxygen accuracy.

For example, the disclosed tolerance needs to be broadened to account for variation in inlet oxygen concentration – a *ventilator* that is indicated for *rated* range "90 % to 100 % O_2" and that does not measure the inlet concentration, and that has a blending accuracy of ±4,5 %, would have a delivered oxygen concentration tolerance of ±5 % when used with oxygen, but might have a delivered oxygen concentration tolerance of ±10 % when configured for use with Oxygen 93. The variation in inlet concentration sums with the blending error term to yield a delivered concentration error.

Alternatively, a *ventilator* with identical blending accuracy of ±4,5 % and that measures the inlet concentration with an accuracy of ±1,5 % might have a delivered oxygen concentration tolerance of ±6 % (and a restricted setting range, 21 % to 90 %), when used with Oxygen 93.

The *manufacturer* is not expected to repeat testing with the oxygen inlet concentration being varied across the *rated* range. It is expected that the effect of variation in the inlet oxygen concentration that is theoretically derived can be used to adjust the results of testing with a known concentration to determine blending accuracy.

Table 201.104 — *Volume-controlled inflation-type* testing

The lung resistance values used in Tables 201.104 and 201.105 are essentially unchanged from the test cases specified in now withdrawn ASTM F1100:90[41]. The only difference has been the addition of five further infant test cases to extend downwards the range of *tidal volume*.

ASTM F1100[41] included a note that resistance values are for 'parabolic resistors'. These are simple devices comprising an orifice plate with a cylindrical hole that are easy to manufacture to good tolerance. However, these have a variation in pressure with flow that follows a quadratic. This results in an effective increase in resistance with flow, much more so than for resistance in the lung, and also more than for resistance of an endotracheal tube (ETT). While linear resistors can be constructed, they typically rely on use of porous media or small-scale laminar-flow structures to achieve a linear pressure-flow profile, and are more difficult to manufacture to close tolerance.

In the first edition of ISO 80601-2-12, the test lung configuration values were retained, however the tables were amended to specify use of linear resistance. At the time, this was thought to be more representative of clinical use, and the increasing availability and use of electronically-controlled test lungs meant that modelling linear resistance was less challenging.

However, it has become clear that in some cases this leads to clinically-implausible test cases, particularly those test cases that use R200 resistance (intended to represent a 3,0 mm ETT) with *tidal volumes* of 30 ml or greater. Test lung resistors are calibrated at a test flow of 1 l/s (60 l/min). Both a parabolic and a linear resistor with *nominal* resistance of R200 provide a pressure drop of 200 hPa at 60 l/min test flow. However, the parabolic resistor will have a pressure drop of only 50 hPa at a test flow of 30 l/min, while the linear resistor pressure drop is 100 hPa. The effect is even more pronounced at lower flow rates – the pressure drop at 15 l/min is 12,5 hPa for the parabolic, versus 50 hPa for the linear, resistor.

In normal breathing patterns, flow in the lung is approximately laminar (owing to the preponderance of the resistance being in the very small scale passages in the lower levels of the tracheobronchial tree). Typical values for total pulmonary system resistance in mouth-breathing humans vary from approximately 20 hPa/(l/s) to 25 hPa/(l/s) in neonates, to less than 5 hPa/(l/s) in adults[56]. These values are significantly increased in restrictive airway disease. However the very high values of resistance found in the *ventilator* test case tables largely represent the resistance of the ETT.

Measurements of pressure drop versus flowrate for seven sizes of ETTs have been published[57]. A 7,0 mm ETT has a resistance at 1 l/s that is close to R10 (10 hPa/(l/s)), however the resistance is lower at lower flow rates, for example at a flowrate of 0,25 l/s the resistance is approximately R4 (4 hPa/(l/s)).

For smaller sizes of ETT, the resistance changes significantly as flow increases above a critical value, which represents the onset of turbulence. Figure AA.1 demonstrates this effect.

The critical flow ranges from 0,25 l/s for a 3,5 mm ETT, to 0,63 l/s for a 7,0 mm ETT. The critical flow is evident in Figure AA.1 as a notch in the pressure curve at approximately 12 l/min (0,2 l/s). Below the critical flow, the pressure drop scales approximately as flow to power 1,3, while above the critical flow the pressure drop scales approximately as flow to power 1,8.

Table AA.1 shows the test cases from Table 201.103 in the previous edition of this document, i.e. ISO 80601-2-12:2011. The first five columns are taken from that table. It should be noted that parabolic resistors are commonly available in a limited number of values, typically Rp5, Rp20, Rp50, and Rp200, and that the table was constructed to use these standard values.

The next two columns show the average flow required (assuming a rectangular flow waveform) and the peak flow required (assuming a worst case linear decreasing flow pattern, terminating at zero flow). The right hand columns show the worst case pressure drop for worst case flow assuming a parabolic resistor, or a linear resistor, respectively.

Key

P is the pressure drop in hPa

Q is the flowrate in l/min

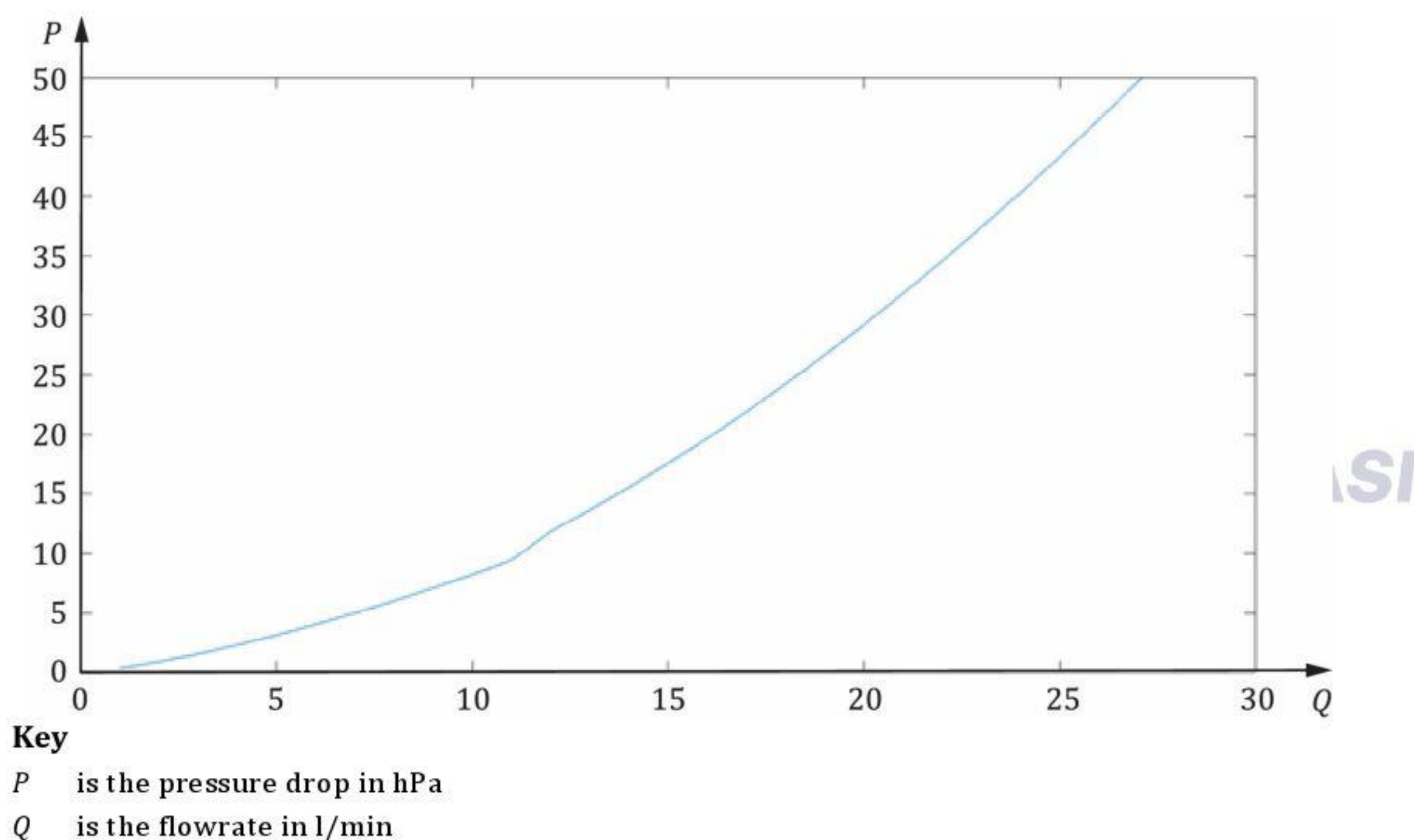



Figure AA.1 — Pressure drop calculation for 3,0 mm ETT, 100 % RH room air at sea level, 37°C, using approach specified in Reference [57]

It is clear that changing the resistor specification from parabolic to linear has very significantly altered the pressure drop due to resistance in all test cases with a *tidal volume* less than 300 ml. In several cases, such as #11, #13 and #15, the resulting pressure drop is far in excess of the pressure drop appropriate to this *patient* model. However, in other test cases such as #18 through #21, the parabolic resistor is clearly too low a resistance to be appropriate.

Calculated pressure drop across a number of sizes of ETT tube at specified flow rates appropriate to that size *patient* are tabulated in Table AA.2, expressed both as actual pressure drop, and as a resistance value (expressed in hPa/(l/s)).

The test cases need to account for both the resistance of the endotracheal tube, and the resistance of the *patient's* pulmonary system. This suggests that for *tidal volumes* of no greater than 20 ml (test cases #16 - #21) resistance values of 50 hPa/(l/s) to 200 hPa/(l/s) remain appropriate. For test cases with *tidal volumes* of 30 ml to 50 ml, representing term neonates or infants, resistance values of 20 hPa/(l/s) to 100 hPa/(l/s) would be appropriate. For test cases of 50 ml or greater,

resistance values should be 5 hPa/(l/s) to 50 hPa/(l/s). Based on this, the resistance values in Table 201.104 and Table 201.105 have been adjusted from the values contained in previous standards.

Table AA.1 — Flow and pressure drop for linear and parabolic resistors

Test # 	*C* ml/hPa	*R* hPa/(l/s)	V_{tidal} ml	*Inspiratory time* s	Mean flow, l/min	Peak flow, l/min	Parabolic ΔP hPa	Linear ΔP hPa
1	50	5	500	1	30	60	5,0	5,0
2	50	20	500	1	30	60	20,0	20,0
3	20	5	500	1	30	60	5,0	5,0
4	20	20	500	1	30	60	20,0	20,0
5	20	20	300	1	18	36	7,2	12,0
6	20	50	300	1	18	36	18,0	30,0
7	10	50	300	1	18	36	18,0	30,0
8	10	20	200	1	12	24	3,2	8,0
9	3	20	50	0,6	5	10	0,6	3,3
10	3	50	50	0,6	5	10	1,4	8,3
11	3	200	50	0,6	5	10	5,6	33,3
12	3	50	30	0,6	3	6	0,5	5,0
13	3	200	30	0,6	3	6	2,0	20,0
14	1	50	30	0,6	3	6	0,5	5,0
15	1	200	30	0,6	3	6	2,0	20,0
16	1	200	20	0,4	3	6	2,0	20,0
17	1	200	15	0,4	2,25	4,5	1,13	15,0
18	1	50	10	0,4	1,5	3	0,13	2,5
19	0,5	50	5	0,4	0,75	1,5	0,03	1,3
20	0,5	200	5	0,4	0,75	1,5	0,13	5,0
21	0,5	200	5	0,4	0,75	1,5	0,13	5,0

Table AA.2 — Flow and pressure drop for linear and parabolic resistors

ETT diameter mm	Test case flow l/min	Pressure drop hPa	Resistance hPa/(l/s)
2,5	0,5	0,36	43
2,5	2,0	1,96	59
3,0	1,0	0,4	23
3,0	4,0	2,3	35
4,0	3,0	0,5	9
4,0	10,0	2,5	15
5,0	5,0	0,4	4,5

ETT diameter mm	Test case flow l/min	Pressure drop hPa	Resistance hPa/(l/s)
5,0	24,0	3,6	9,0
7,0	20,0	0,6	1,8
7,0	60,0	3,7	3,7

Subclause 201.12.1.102 — *Pressure-control inflation-type*

b) 3)

Table 201.105 — *Pressure-control inflation-type* testing

See rationale for Table 201.104.

See rationale for 201.12.1.101 b) 3).

Subclause 201.12.1.104 — *Inspiratory volume* monitoring

Evidence is accumulating that both volutrauma and barotrauma can result in respiratory morbidity and affect long-term respiratory outcome. Overstretching of the lung results in a decrease of the compliance in the respiratory system. A continual overstretching results in an increase in the water content of the lungs and microscopic evidence of alveolar and interstitial oedema, alveolar haemorrhage and neutrophil infiltration[36]. The immature lung is especially vulnerable to injury due to overstretching[37]. Volutrauma has been characterized by airway modelling and airway hyper-responsiveness in infant rats[38]. In addition the early onset of airway hyper-responsiveness is a predictor of bronchopulmonary dysplasia in human infants[37], a condition resulting in permanent lung injury[19]. As a result, the *healthcare professional operator* needs to know both the *inspiratory volume* and *airway pressure* to be able to assess the adequacy of the *patient's* ventilation.

As with the measurement of *airway pressure*, the site of the volume measurement is not specified, but the value is required to be referenced to the *patient-connection port* (additional information is found in the rationale for 201.12.1.102). The permissible errors in measurement of *airway pressure* and *inspiratory volume* are reasonable for *patients* that require more than 50 ml *inspiratory volume*, i.e. there is little *risk* associated with under-ventilating such *patients*. This is less true for smaller *patients*, particularly those requiring *tidal volumes* of less than 50 ml, with stiff lungs in a *volume-control inflation-type*.

For neonatal and infant *patients*, it is not practicable to mandate an accuracy specification for volume monitoring. In *ventilator* use-cases that do not include a flow sensor at the *patient-connection port*, this can only be estimated by subtracting the *tidal volume* estimated as lost to the compliance of the *VBS* from the *tidal volume* as measured by flow sensors in the *ventilator*. For those *patients* requiring *tidal volumes* of less than 50 ml, this circuit compliance volume can significantly exceed the tolerance mandated in this subclause.

There can be clinical reasons why it is not appropriate to use a flow sensor at the *patient-connection port* for some *patients*. Such a flow sensor would add a dead space to the *VBS*, which increases rebreathing, and imposes an additional ventilatory burden. In addition, the mass of the flow sensor can contribute to unintended extubation, which can contraindicate use in some infants.

As a consequence, the accuracy specification for volume monitoring with *tidal volumes* of less than 50 ml has been left as a *manufacturer* disclosure.

Subclause 201.12.1.105 — Response of the *ventilator* to an increase in O_2 concentration

It is important that changes in the delivered oxygen concentration can be made without major delay. This is especially relevant in cases where a rapid increase of the inspired oxygen concentration is necessary for *patient* care. For instance, it is common practice to preload the *patient* with high concentrations of oxygen for a brief period prior to open suctioning. Depending on the design of the *ventilator* and depending on the settings, significant delays can occur.

The committee could not develop a maximum delay as there are too many possible clinical scenarios. However, the *healthcare professional operator* needs to know how a *ventilator* will respond, particularly to a request for a sudden increase in oxygen concentration delivery.

As a result, a test method has been developed. The results of this test are required to be disclosed in the instructions for use so that an *healthcare professional operator* can effectively care for the *patient*.

Subclause 201.12.4.102 — Measurement of *airway pressure*

Additional information is found in the rationale for subclause 201.12.1.104.

The site in the *VBS* at which pressure is sensed varies from *ventilator* to *ventilator*. Generally, the *manufacturer* chooses one of two strategies:

— measuring the *airway pressure* by direct sampling at the *patient-connection port*: or

— indirectly estimating the pressure at the *patient-connection port* by measuring the pressures at two locations in the *ventilator*, on the inspiratory side of the *VBS* (at the "to *patient*" port) and on the expiratory side of the *VBS* (at the "from *patient*" port), and, after mathematical manipulation, averaging the two values.

Even if the first strategy is chosen, the actual pressure transducer will be located inside of the *ventilator enclosure* with narrow-diameter "plastic" tubing linking the pressure-sampling port at the *patient-connection port* to the sampling nipple on the pressure transducer. And for safety reasons a separate transducer will likely measure the pressure on the inspiratory side at the "to *patient*" port. The displayed *airway pressure,* however, is always expected to estimate accurately the true value that would be measured at the *patient-connection port*. Pressure measurement via the first strategy accurately reflects the true *airway pressure* within the error of the pressure transducer.

If the *manufacturer* selects the second strategy for the prediction of the true *airway pressure*, at least two methodologies can be used to arrive at estimates of this *airway pressure*.

Assuming that during inspiration the gas in the expiratory limb is essentially stagnant, one can conclude that the pressure measured on the expiratory side of the *VBS* reflects the true *airway pressure*. And conversely during exhalation, if one assumes stagnant conditions in the inspiratory limb, the pressure measured on the inspiratory side of the *VBS* can be taken as the *airway pressure*. However, if "bias" or "base" flows during inspiration and exhalation result in significant pressure losses across these individual limbs, these pressure losses need to be estimated. The *airway pressure* on the inspiratory side, $P_Y^I(t)$, can be approximated by Formula (A.1):

$$P_Y^I(t) = P_I(t) - \dot{V}_I(t) \times R_I \quad \text{(A.1)}$$

where

$P_I(t)$ is the measured pressure on the inspiratory side of the *VBS*,

$\dot{V}_I(t)$ is the flow in the inspiratory limb, and

R_I is the resistance of the inspiratory limb.

The *airway pressure* on the expiratory side, $P_Y^E(t)$, can be approximated by Formula (A.2):

$$P_Y^E(t) = P_E(t) + \dot{V}_E(t) \times R_E \quad \text{(A.2)}$$

where

$P_E(t)$ is the measured pressure on the expiratory side of the *VBS*,

$\dot{V}_E(t)$ is the flow in the expiratory limb, and

R_E is the resistance of the expiratory limb.

Taking the average of the inspiratory and expiratory pressures is shown in Formula (A.3), which arrives at the best estimate the *airway pressure*, $\overline{P}_Y(t)$.

$$\overline{P}_Y(t) = \frac{P_Y^I(t) + P_Y^E(t)}{2} \quad \text{(A.3)}$$

The application of this last method requires a method to estimate R_I and R_E. With appropriate algorithms and regular cross checking of the two pressure transducers, the reliability and accuracy of $\overline{P}_Y(t)$ is assured.

Subclause 201.12.4.103 — Measurement of expired volume and low-volume *alarm conditions*

It is desirable to have a fast responding measurement of volume and narrow *alarm limits*. However, as there is often considerable variation in a *patient's* ventilatory pressures and volumes, narrow *alarm limits* inevitably lead to clinically insignificant *alarm conditions*. As a result, *healthcare professional operators* choose to set wide *alarm limits* to reduce the number of insignificant *alarm conditions* despite the fact that this can compromise *patient* care when there is a prolonged small change in their ventilation. Therefore, it is recommended that a *ventilator* be designed to initially use a lower priority *alarm condition*, which escalates to a higher priority if the *alarm limit* violation persists. The initial *alarm condition* priority and the priorities and timing of the escalation should be determined by the severity of the potential *harm* to the *patient* in combination with the length of time that the *healthcare professional operator* has to prevent the *harm* from occurring.

Subclause 201.12.4.104 — Expiratory end-tidal CO_2 *monitoring equipment*

The monitoring of expiratory end-tidal CO_2 is employed clinically as a surrogate for arterial CO_2 tension. It therefore provides an alternative to monitoring expired *tidal volume* in assessing the adequacy of ventilation of the lungs. However, in the event of an occlusion or leak within the *VBS*, minute ventilation can be significantly reduced, while arterial CO_2 rises. This can result in monitored end-tidal CO_2 values that remain within the clinically acceptable range as the *patient tidal volume* is reduced below the level of physiologic dead space. The committee did not believe

that safety could be ensured through use of monitoring of end-tidal CO_2 unless either monitoring *inspiratory volume* or expired volume was also in use.

It is not intended that this constrain a *manufacturer* to integrate the CO_2 *monitoring equipment* into the *ventilator*. This allows for cases such as when the end-tidal CO_2 *monitoring equipment* is integrated within a vital signs monitor from a separate *manufacturer*.

Subclause 201.12.4.105 — *Maximum limited pressure protection device*

When developing this edition of the document the committees carried out a re-evaluation of the current level of *maximum limited pressure*.

For several decades, international standards have specified the *maximum limited pressure* under *single fault conditions* of 125 hPa (125 cmH_2O). However, limiting the lung pressure to 125 hPa (125 cmH_2O) is not considered as lung protective. Therefore, it has been suggested that the *maximum limited pressure* should be reduced.

In a general population, the lung protective ventilation strategy involves keeping *tidal volumes* at 4 ml/kg to 6 ml/kg of predicted body weight (PBW) and preventing lung pressure from exceeding ~28 hPa (28 cmH_2O) and "driving" pressures from exceeding 15 hPa (15 cmH_2O). However even while applying this lung protective strategy as described above a limited number of *patients* need extremely high pressures at the *patient-connection port* (i.e. >80 hPa (80 cmH_2O)) due to the extremely high resistance of their airways (e.g. *patients* suffering from an acute severe asthma).

Another clinical strategy considered is the use of a high *set rate* in order to minimize lung delta pressure while maintaining adequate CO_2 removal. This requires a short inspiratory duration which in turn requires a high flowrate that requires a pressure at the *patient-connection point* that is significantly higher than the pressure in the *patient* lung.

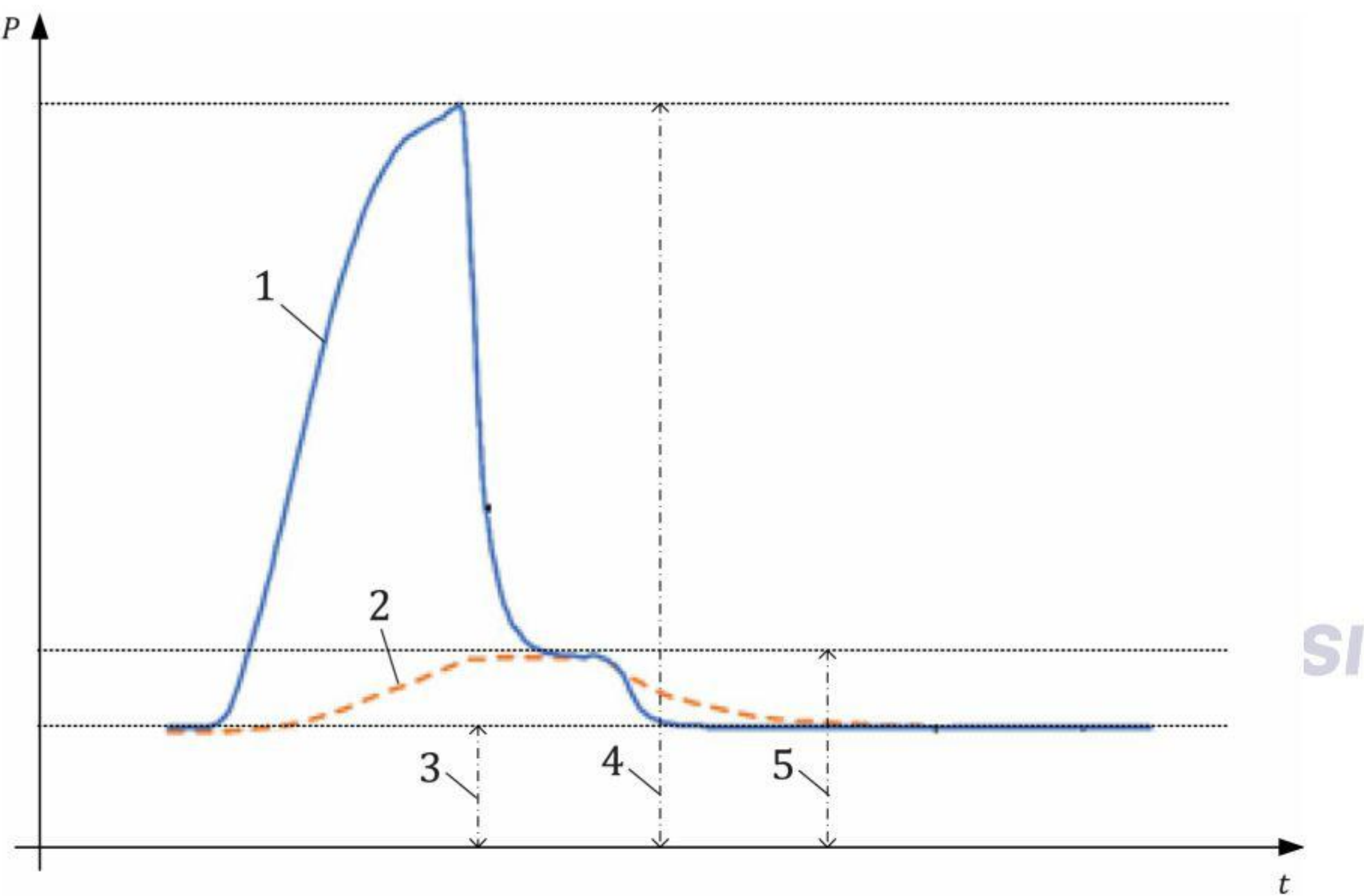
High peak pressure at the *patient-connection port* can also be necessary for short periods for lung recruitment manoeuvres in obese *patients*.

The Figure AA.2 illustrates a pressure waveform during *volume-control* breath delivery to a *patient* with acute severe asthma. This shows a high peak pressure at the *patient-connection port* but a much lower pressure to which the lung of the *patient* is exposed. The high peak *airway pressure* at the *patient-connection port* is not injurious to the lung, as it does not reach the *patient's* lung. However, if lung would be exposed to these non-acceptable pressures, the lung would be injured.

Considering the need to control the *risk* of a potential barotrauma (i.e. to reduce the *maximum limited pressure* the *patient* will be exposed to under *single fault conditions* as far as possible) but also considering the need to provide higher pressures under specific clinical conditions, the committees have developed a new concept which accommodates both the safe pressure limitation under *single fault conditions* for each individual *patient* and the clinical needs of higher pressures for a specific group of *patients*.

A review of incident databases did not identify any data demonstrating enhanced safety with a general pressure limitation lower than 125 hPa (125 cmH_2O). Therefore increased *patient* safety would not be achieved by reducing the *maximum limited pressure* below 125 hPa (125 cmH_2O), and such a reduction would prevent required treatment of certain *patients* and diagnoses.

This document defines a high pressure *alarm condition*, with an *alarm limit* that is configurable by the *operator*. Standard clinical practice is to set the high pressure *alarm limit* to a value that is a safe maximum peak *airway pressure* for the *patient*.

The *maximum limited pressure* is a secondary means of protection which becomes effective under *single fault condition*. In order to apply an appropriate level of *maximum limited pressure*, while not preventing effective ventilation with pressures necessary for the specific case, the committees decided to link the *maximum limited pressure* to the *operator*-configured high pressure *alarm limit*.

Key

1 *airway pressure*, P_{aw}

2 lung pressure, P_{lung}

3 *BAP*

4 maximum *airway pressure*, $P_{aw,max}$

5 maximum lung pressure, $P_{lung,max}$

Figure AA.2 — Pressure waveforms as a function of time during *volume-controlled* breath delivery to a *patient* with acute severe asthma

It is very common to use active controlled valves for limiting the maximum pressure. These valves open with a certain response time, which could result in a short pressure overshoot. When open the flow results in a pressure differential. Both effects together with the tolerance of the pressure control requires there to be a margin between the high pressure *alarm limit* and *maximum limited pressure*. Taking account of the technology available the committee determined that a margin of 20 hPa (20 cmH_2O) between the high pressure *alarm limit* and *maximum limited pressure* would be sufficient.

In order to mitigate for unintentionally inappropriate settings, causing the high pressure *alarm limit* to go above at 60 hPa (60 cmH_2O) or 20 hPa (20 cmH_2O) above the *operator*-set pressure, an *operator* interaction requiring a clear and deliberate action, is introduced. See rationale to 201.12.4.106.

Subclause 201.12.4.106 — High *airway pressure alarm condition* and *protection device*

The high *airway pressure alarm condition* can occur in several scenarios, with different appropriate responses. It should be noted that it is implicit that in *normal condition*, the exhalation resistance of the *VBS* (including breathing circuit, filters, and exhalation valve) is sufficiently low so that the pressure can return to set *BAP* within one *respiratory cycle* of the end of a *ventilator* inspiration.

e)

Considering the reported incidents of *patient harm* associated with inappropriate setting of the high *airway pressure alarm limit*, the committees considered options to ensure that the *alarm limit* is set appropriately to reduce *risk* of barotrauma.

The great majority of *patients*, ventilated by a *ventilator* specified by this document, will not need more than a 60 hPa (60 cmH_2O) high pressure *alarm limit* for sufficient ventilation. Therefore the committees determined that an unintentional setting in excess of 60 hPa (60 cmH_2O) would be inappropriate.

In order to control the *risk* of unintentional settings, causing the high pressure *alarm limit* to be set above 60 hPa (60 cmH_2O) or 20 hPa (20 cmH_2O) above the *operator*-set pressure, an *operator* interaction requiring a clear and deliberate sequence of actions, was introduced to set the high pressure *alarm limit* to values in excess of 60 hPa (60 cmH_2O) or 20 hPa (20 cmH_2O) above the *operator*-set pressure.

f)

Patient cough

A cough is a transient forced expiration due to involuntary contraction of the abdominal muscles and opening of the glottis and vocal chords, resulting in a very rapid expiratory flow of short duration. This is most commonly triggered by pulmonary irritant receptors, and is a defensive mechanism that ejects foreign matter from the bronchi and trachea.

This action triggers a rapid but transient increase in pressure at the *patient-connection port*. The pressure elevation is generated by the *patient* respiratory muscles. In this scenario, it can be appropriate to transition to exhalation, as this would assist the forced expiration and clearance of foreign material. However, the volume of air ejected has come from the lungs, and the normal operation of the *ventilator expiratory phase* control of pressure would be sufficient to restore pressure to a value close to set *BAP*, within the normal exhalation period. There is no clinical reason to open a pressure-relief valve.

Patient forced expiration

In some cases, a *patient* can make a forced expiratory effort during the *ventilator inflation phase*, resulting in a pressure increase at the *patient-connection port*. As this is a *patient*-generated pressure, the same rationale applied to cough would apply to this scenario, and transition to the exhalation phase is an appropriate and sufficient response. Even in the worst case, the exhaled volume would be unlikely to exceed twice the normal exhaled volume, and the time required to reduce the pressure to set *BAP* would not significantly exceed one *respiratory cycle*.

Inappropriate volume for *patient* compliance

In a *volume-control* or volume-targeted *ventilation-mode*, pressure can exceed the high *airway pressure alarm limit* due to a reduced pulmonary compliance. In this scenario it would be preferable to apply a pressure limitation (with a threshold less than the high *airway pressure alarm limit*). However in the absence of this function, the appropriate action would be to transition to the exhalation phase. As the *inspiratory volume* is not increased, there is no reason why the normal operation of the *ventilator* in the *expiratory phase* would not reduce the *airway pressure* to set *BAP* within one *respiratory cycle*.

Inspiratory limb occlusion

In this *single fault condition*, the *patient* is not subject to high pressure. *Ventilators* that do not incorporate a pressure monitoring line from the *patient-connection port* might be unable to differentiate this from a high *airway pressure* state. Because the *patient* is not subjected to the high *airway pressure*, the action defined in 201.12.4.108 (obstruction *alarm condition*) is appropriate to control the *risk*.

Expiratory limb, *breathing system filter* or expiratory valve occlusion

For most software-controlled *ventilators*, this only results in a high *airway pressure alarm condition* if it occurs during the *expiratory phase*, as the exhalation valve remains closed during *ventilator* inspiration. In some cases (such as a ‘pressure limited’ *ventilation-mode*), the *patient* pressure can exceed the *alarm limit* if the occlusion prevents the *maximum limited pressure protection device* from operating.

Terminating *gas output port* flow – either by terminating the *inflation phase*, or terminating the base or *continuous flow* – causes the pressure to stop increasing, but might not result in the pressure falling below the *alarm limit*. This constitutes the ‘action to cause the pressure to start to decline’. If the pressure fails to return close to set *BAP* within one *respiratory cycle*, this is evidence that the expiratory resistance is excessive, and the *ventilator* should provide an alternative means to relieve the pressure. Typically this would involve opening some form of ‘safety valve’ in the inspiratory part of the *VBS*. Assuming that the inspiratory limb of the circuit has comparable resistance to the expiratory limb, it can then take one further *respiratory cycle* to restore pressure at or below set *BAP*. Hence the committees have specified that the pressure is required to be reduced to set *BAP*, or atmospheric pressure level, within no more than two *respiratory cycles* or 15 s.

Flow delivery ‘fails open’

In *single fault conditions* such as a mechanical failure of a pressure regulator or a flow control valve, or a failure of software control of a flow source, resulting in uncontrolled flow of gas to the *ventilator gas output port*, transition to the *expiratory phase* (which opens the exhalation valve) should be sufficient to control the *risk*. However, the pressure might not reach the limit within 200 ms. If the pressure remains above the high *airway pressure alarm limit* (for example because of a catastrophic flow valve failure) it can then be appropriate to also open some form of pressure-relief valve to divert the *gas output port* flow and restore the *patient-connection port* to atmospheric pressure.

h)

Atmospheric pressure

In *normal condition*, termination of *ventilator* inspiration, and the normal action of the expiratory valve, allows pressure to be relieved to *PEEP* within one *respiratory cycle* without loss of control of *PEEP*. *Normal condition* would include any *patient*-generated effect. However, if there is a *single fault condition*, such as an obstruction of the breathing circuit or a flow delivery fault, other means can be required to reduce the pressure, and in this scenario it is not expected that the *ventilator* is able to maintain control of *PEEP*.

Set BAP level

As noted above, the worst-case time required to reduce the *airway pressure* to a value less than or equal to set *BAP* is two *respiratory cycles*. To account for the possibility that the mandatory *set rate* has been set to a value significantly less than the *patient's* normal resting breathing rate, the committees have limited the recovery time to a maximum of 15 s. This reflects literature that shows typical breathing rates in adults[42], including geriatric populations[43], that are rarely less than 10 breaths/min, and hence would require no more than 12 s for two *respiratory cycles*.

Subclause 201.12.4.108 – Obstruction *alarm condition*

Sustained elevated *airway pressure* levels can cause hazardous increases in intra-thoracic pressure. Such pressure increases can result in decreased venous return, reduced cardiac output and a subsequent drop in arterial blood pressure. Obstruction of the expiratory limb is the most common obstruction in a *ventilator*. The obstruction of the expiratory limb *alarm condition* should be designed to detect promptly a reduced expiratory flow due to an increased resistance in the expiratory limb.

The nature or duration of an occlusion in the expiratory limb of the *VBS* cannot be predicted. Assuming that the occlusion is severe and the safety valve opens quickly, the *patient* is not exposed to potentially injurious high pressures, although at the likely expense of the loss of *PEEP*. Further inspirations, whether or not assisted by the *ventilator*, necessitate rebreathing the previously exhaled gas trapped in the inspiratory limb. Given these considerations and their consequences, the associated *alarm condition* is required to be at least *medium priority*. Even if the *ventilator* is highly sophisticated, the presence of an occlusion in the expiratory limb of the *VBS* represents a significant corruption of the *ventilator's* ability to provide essential respiratory support to the *patient*, which requires prompt action by the *healthcare professional operator*.

Examples of causes for continuing *airway pressure* include a malfunctioning expiratory valve, kinked tubing and expiratory filter blockage. Nebulised[16] drugs can block expiratory filters within a short time.

Other consequences of incomplete expiration (increased peak *airway pressure* or decreased ventilation) can be detected and indicated by other *alarm conditions* required by this document. Practice shows that clinically used *alarm limits* are not always sensitive enough to provide early and specific detection of this potentially *hazardous situation*.

Subclause 201.12.4.109 — Disconnection *alarm condition*

Disconnection of the *ventilator breathing system* is a frequent occurrence in the critical care environment, and yet the only reference on the previous edition of this document is a reference

in 201.13.2.101 to disruption of the gas delivery to the *patient-connection port* from the *ventilator*.

It is recognized that disconnection leads to a loss of gas exchange, with the possibility of significant *harm* or death[44]. Many current critical care *ventilators* generate a *technical alarm condition* when this occurs. This amendment adds a mandatory requirement to provide such a disconnection *alarm condition*.

Implementation of a disconnect *alarm condition* can use a variety of technological means to detect gas flow into and out of the lungs, and these can differ between different groups of *patients*. Where the disconnect *alarm condition* detection mechanism uses information from one or more external sensors, such as for expired CO_2, the requirement from Clause 13 of the General Standard for single fault safety applies. Loss of information from an external sensor would need to be assessed as a *single fault condition*.

Detection of disconnection of the breathing *gas pathways* between the *ventilator* and the *patient-connection port*, or disconnection at the *patient-connection port*, is mandatory.

In some *patient* groups, and particularly in neonates ventilated with a narrow lumen endotracheal tube, it might not be practicable to reliably detect decannulation without using a sensor placed between the *patient-connection port* and the airway device. For example an expiratory flow or end-tidal CO_2 sensor.

However there can be clinical reasons why this is not appropriate. Use of either a flow sensor or a mainstream $EtCO_2$ sensor adds dead space to the airway device, which can be very significant relative to the desired *tidal volume*. This would increase rebreathing of exhaled gases, and impose an additional ventilatory burden. This has been demonstrated to prolong weaning time and worsen *patient* outcome[58].

In addition, the mass of the sensor attached to the airway device can increase the incidence of unintended extubation.

When using a diverting (sidestream) expired CO_2 monitor, the monitor removes a fixed flowrate of gas from the *patient-connection port*. This can exceed the spontaneous inspiratory flow for an infant *patient*, and thereby prevent use of *patient*-triggered *ventilation-modes*, resulting in a higher imposed work of breathing and *patient-ventilator* asynchrony.

As a consequence, the *operator* needs to retain the ability to select which monitoring devices are attached to the *VBS*, while also being aware of any limitation that the adopted configuration imposes on the operation of the *alarm system*. For this reason, this has been added to Clause 206 to ensure that the *usability process* is applied to this scenario.

Critical care *ventilators* are intended for use in the critical care environment. These settings provide specialized care for *patients* with conditions that can be life-threatening and who require constant monitoring in a *professional healthcare facility*. Not all *patients* who are cared for in the critical care environment are *ventilator-dependent*, and as a result critical care *ventilators* can be used to augment the ventilation of spontaneously breathing *patients*.

Although some *manufacturers* have chosen to provide separate *ventilation-modes* for *ventilator-dependent* and non-*ventilator-dependent patients*, this is discouraged as it leads to *operator* confusion. According to ISO 19223, *ventilation-modes* are classified by the types of *inflations* that

are provided, the pattern of initiation, and independently of the intended *patient* or airway interface.

In those *patients* who are not *ventilator-dependent*, disconnection cannot require prompt attention from the *operator*. Alarm fatigue is well-documented in the clinical setting[45], and can lead to delayed response to those *alarm signals* that really are critical, including *alarm signals* from the *ventilators* used for *ventilator-dependent patients*[46]. It is desirable to allow the *operator* to inactivate this *alarm condition* to avoid distracting caregivers from other more critical events.

This document does not address how the *operator* confirms whether a particular *patient* is *ventilator-dependent* prior to inactivating the disconnection *alarm signals*. Many implementations are possible, for example, this information can be captured during *patient* setup; or it can be included as a prompt during the *process* of inactivation. The *manufacturer* is required to perform *usability* testing in order to validate the effectiveness of their implementation.

Subclause 201.12.101 — Protection against accidental adjustments

Unacceptable *risks* to the *patient* can occur as a result of accidental adjustments of operating controls or turning off the *ventilator*. To control this *risk*, the *operator-equipment interface* should be designed to prevent accidental adjustments. The *usability engineering process* is used to ensure that these *risks* are reduced to acceptable levels. Example methods could include mechanical *risk control* techniques such as locks, shielding, friction-loading and detents; pressure-sensitive finger pads; capacitive finger switches; and microprocessor-oriented “soft” *risk controls*; and a specific sequence of key or switch operations.

Subclause 201.13.2.101 — Additional specific *single fault conditions*

a)

Disruption of the gas delivery to the *patient* independent of the root cause for the disruption (e.g. by disconnection or blockage of the inspiratory breathing / tubing system) is the most reasonably foreseeable event in the daily practice of ventilation around the world that might quickly lead to serious irreversible injury or the death of a *ventilator-dependent patient*.

b)

Disruption of the gas flow pathway between the *patient* and the *ventilator* independent of the root cause for the disruption (e.g. by disconnection or blockage of the expiratory breathing / tubing system) is the most reasonably foreseeable event in the daily practice that, depending on the *VBS* in use, might lead to pressure loss. This can consequentially lead to the inability to build up a *VBS* pressure sufficient to ventilate the *patient,* which in further consequence might lead to serious irreversible injury or the death of a *ventilator-dependent patient*.

c)

Operation of a *ventilator* without an *operator*-detachable *breathing system filter* in place is considered reasonably foreseeable when considering those parts of the *VBS* that might become contaminated with body fluids or by contaminates carried by expired gases. If a *ventilator* can operate without the *breathing system filter*, then one has to assume that it has been operated without the *breathing system filter* and therefore those parts of the *VBS* might have been contaminated. Additional information is found in the rationale for 201.11.6.6.

Increased resistance and blockage of a *breathing system filter* when used together with nebulization[16] or humidification is also considered as failure of an *operator*-detachable *breathing system filter*.

d)

Operation of a *ventilator* using an *operator*-detachable remote control or monitoring module is considered as a state of the art option of today. Independent of how the communication between the "ventilator module" and the remote control or monitoring module is facilitated (e.g. wired or wireless) this communication needs be so designed and constructed that a failure or loss of this communication does not cause an unacceptable *risk* to the *patient*. Further this communication (e.g. between the "ventilator module", the remote control or monitoring module, the *distributed alarm system* or a simple remote *alarm signal* communicator) also needs designed as *single fault safe*.

Subclause 201.13.2.102 — Failure of one gas supply to a *ventilator*

This subclause addresses the *hazardous situation* created when an entire unit (e.g. the whole critical care unit or all of the operating theatres) experiences simultaneous failure of multiple *ventilators* caused by the loss of a single pressurized gas source where at least one gas source is provided by a pressurized *medical gas pipeline system*.

EXAMPLE 1 A *ventilator* is connected to both air and oxygen *medical gas pipeline systems* and one of the *medical gas pipeline systems* fails. The *ventilator* then uses the other *medical gas pipeline system* to supply gas.

EXAMPLE 2 A blower-based *ventilator* is connected is to an oxygen *medical gas pipeline system* and that *medical gas pipeline system* fails. The *ventilator* then uses the room air provided by its blower.

Subclause 201.13.2.103 — Independence of ventilation control function and related *risk control* measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

Subclause 201.13.2.104 — Failure of *functional connection* to a *ventilator* control or monitoring means

Independent how the *functional connection* between the "ventilator module" and the remote control or monitoring module is facilitated (e.g. wired or wireless) this *functional connection* needs to be so designed and constructed that a failure or loss of the *functional connection* does not cause an unacceptable *risk* to the *patient*.

First of all this means that the safety of the *patient* is not degraded by the loss of the *functional connection*, (i.e. the "ventilator module" continues to ventilate the *patient* without any change of the ventilation parameters, without any change of setting of safety means and without any change of the setting of *alarm limits*). Further, the *healthcare professional operators* in both locations where these modules are located need to be made aware by *alarm signals* about the loss of this *functional connection* (i.e. there is a need for *alarm signals* on both sides of the *functional connection*—at the "ventilation module" and on any other remote control or monitoring module or the *distributed alarm system* or the simple remote *alarm signal* generator).

Subclause 201.15.3.5.101.1 — Shock and vibration (robustness)

The intention of these tests is to assess mechanical stresses on the *ventilator* in *normal use* and not to assess the suitability of the design for the *expected service life* or fatigue.

ME equipment, including *ventilators*, in *normal use*, used within a *professional healthcare facility*, or *home healthcare environment* will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, *ME equipment* intended to be used in a *professional healthcare facility* needs to be robust enough to withstand the vibration and shock testing described as level 7M1 by IEC 60721-3-7[47]. IEC 60721-3-7 indicates that this class applies within, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

In reviewing the random vibration tests of IEC 60068-2-64:2008, the committee determined that the environment included careful handling in vehicles (including airborne vehicles). Since a critical care *ventilator* is not intended for such environments, the maximum frequency of the acceleration amplitude was limited to 500 Hz which is more reflective of non-vehicle environments.

Subclause 201.15.3.5.101.2 — Shock and vibration for a *transit-operable ventilator* during operation

Transit-operable ventilators (those intended to operate while the *patient* is being transported within a healthcare facility) are expected to maintain *basic safety* and *essential performance* while they are being moved. Some degradation is permitted, but the *patient* is expected to continue to be adequately and safely ventilated. Rationale for 202.8.101 contains additional information regarding appropriate acceptance criteria for *essential performance*.

Subclause 201.16.2.101 — Additional general requirements for *accompanying documents* of an *ME system*

Many respiratory gas *humidifiers* control their humidification output by servo controlling the temperature of a water bath to achieve a set gas temperature at the *humidifier* chamber outlet. This temperature is frequently defined to be a function of gas flowrate as measured by the *humidifier*, and is defined to target a desirable absolute humidity – the rate of evaporation of water and the rate of heat transfer from the water to the air are closely correlated. This works provided the input gas temperature is below a threshold. For example, for one leading *manufacturer* of *humidifiers*, the water vapour output starts to reduce when the input gas temperature exceeds 27 °C.

A *ventilator* that incorporates a blower to provide a source of breathing air drawn from an air intake inevitably increases the temperature of the air above the intake temperature. The extent of this rise in temperature will depend on the set FiO_2 (and hence the proportion of the breathing gas that has been compressed), the blower outlet pressure (which can significantly exceed the *ventilator gas output port* pressure), the *ventilator set rate*, *BAP*, and set *Δ inspiratory pressure* or *tidal volume*, and the efficiency of the blower technology used.

This has been confirmed in published bench study[59]. This study confirmed that with unfavourable conditions, specifically *humidifier* chamber inlet gas temperatures above 37 °C, *humidifier* output could fall well below recommended minimum levels of 20 mgH_2O/l.

For a *ventilator* capable of generating an elevated gas temperature at the *gas output port*, the *responsible organization* needs to have information available to allow them to determine whether the *humidifier* is likely to remain effective.

Subclause 201.101.1 — Protection against reverse gas leakage

These conditions are necessary to maintain *patient* safety by protecting the *medical gas pipeline system* from contamination via reverse flow.

The basic requirements of this subclause were introduced into standards more than a decade ago because of the *harm* due to reverse gas leakage that was known to have occurred in connection with medical devices that use multiple gas sources.

With devices fitted with multiple *gas intake ports* for the same gas, the *hazardous situation* results from the undetected loss of backup gas supplies due to back leakage into the primary supply. With *gas intake ports* for different gasses, the *hazard* is contamination of one gas source by gas from another source. The contamination *hazard* is particularly likely to occur while the medical device is left in a condition where it is connected to the gas supplies but is not drawing flow from the gas supply system.

Ventilators are frequently equipped with multiple *gas intake ports* either to achieve a greater flow or to use a local backup supply, e.g. a gas cylinder, in parallel with a *medical gas pipeline system* supply. With such systems the backup supply could be depleted prematurely during use or, when connected but not in use, could deplete without detection and not be available when required in an emergency.

With a *ventilator* equipped with more than one different *gas intake port*, even very small leakages from one of the gas systems to the other can cause considerable contamination in a *medical gas pipeline system* over extended periods during which little flow is withdrawn.

More than 10 y of experience has demonstrated that these requirements are effective *risk control* measures.

Subclause 201.101.2.2 — Filter

The intention of filtration of the gas from the *high-pressure inlet port* is to protect the sensitive components (e.g. flow sensors) of the *ventilator gas pathways* from particles. This gas is provided from a *medical gas pipeline systems* or from gas cylinders.

The standards for high-pressure oxygen compatibility[8] and pressure regulators[29] require input filtering that prevents particles greater than 100 μm from entering. This filtering minimizes particles as means to control the *risk* of ignition by high velocity particles in a pressurized, oxygen enriched environment. These standards also emphasize the need to proper filter material.

Despite these requirements, in the following cases particles with larger sizes could occur:

— particles collected in *high-pressure input ports* and port connectors;

— *high-pressure input ports* of *ventilators* while disconnected; or

— malfunction of *medical gas pipeline systems*, medical air compressors, oxygen concentrators or filters.

Depending on the design of a specific *ventilator* (e.g. in case that particle-sensitive sensors are used) significantly smaller filter sizes than 100 µm can be required.

Subclause 201.101.3.1 — General

Non-standard *VBS* connectors can represent an unacceptable *risk* as attempts are made to fit a standard *VBS* to a *ventilator* in an emergency situation. Non-standard *VBS* connectors can cause leaks if used with similar but not compatible connectors.

Subclause 201.101.3.2.5 — *Accessory* port

The use of Luer taper or Luer-lock connectors conforming with ISO 594-1:1986[49], ISO 594-2[50] or ISO 80369-7:2016[51] are not permitted for use for connection with the *gas pathways* of a *VBS* as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

Subclause 201.102.1 — General

It is the responsibility of the *manufacturer* of a *ventilator breathing system*, its parts or *accessories* to verify that their product conforms with the requirements of this document.

Subclause 201.102.4 — Water vapour management

Water management refers to the complete *process* by which moisture, in the form of water vapour, is added to the breathing gas delivered to the *patient's* lungs and the *process* by which humidified breathing gas is conducted back to the *ventilator's* expiratory system and exhausted to the room. Intrinsic to this *process* is the necessity to remove bulk water due to condensation of moisture attributable to pressure and temperature changes in the *VBS*. Even if breathing gas reaches the *patient-connection port* without any added moisture, the expired breathing gas directed back to the *ventilator* will contain some moisture. Water management in the *VBS* requires attention, whether or not the *VBS* contains an active *humidifier*, with or without heated wires in the inspiratory or the expiratory limbs of the *VBS*, or a passive or an active *HME* at the *patient-connection port*.

Proper management of the *patient's* airway secretions and mucociliary transport system requires that the *ventilator* compensate for the humidity deficit caused by intubation, which bypasses the upper airways where the normal humidification *process* would begin. Excess moisture delivered to the *patient-connection port* can flood the cilia located in the bronchial airways, diminishing their ability to move mucus toward the trachea. On the other hand insufficient humidification of the inspired breathing gas dries the bronchial airways, which leads to thickening of the mucous secretions and likely increased airway resistance or worse. A balanced approach to humidification is needed to maintain healthy cilia. Liquefied mucus can be readily aspirated using a *suction catheter*.

Optimal humidification of the *patient's* airways results from an understanding of the physics of the techniques chosen to add water vapour to the inspiratory gas stream. Depending on the system selected for delivering humidified breathing gas to the *patient* (for example, active vapour *humidifier* with or without heated wires, a passive or active *HME*), condensate can accumulate in the inspiratory limb of the *VBS*. If condensation occurs, the *VBS* will need to provide a method by which the liquid can be removed.

In all but the most unusual circumstances, gas leaving the alveoli is saturated at 37 °C. Rainout persists as the moist gas cools and moves toward the *patient-connection port*, and is conducted back to the *ventilator*. If an *HME* is fitted at the *patient-connection port*, approximately 50 % to 70 % of the water vapour will be trapped in the *HME*. Whatever the configuration of the expiratory limb of the *VBS*, the water vapour content of the exhaled gas will be significant, nearing saturation. Without heated wires, the returning gas cools, causing significant condensation. As in the inspiratory limb, this liquid needs to be removed. The presence of heated wires in the expiratory limb lessens or eliminates condensation before the expired gas enters the *gas return port* of the *ventilator*, but from this point to the *exhaust port* the gas tends to cool further, so more moisture will condense. The *VBS* needs to include some means to manage this additional condensed water.

Subclause 201.102.7.1 — Leakage from complete *VBS*

Assuming that the leakage flow can be modelled as if an ideal orifice were producing it, then the leakage flowrate would follow Formula (AA.4).

$$Q_{\text{leak}} = G \times \sqrt{P} \qquad \text{(AA.4)}$$

where

G is the orifice conductance and

P is the driving pressure.

Using the leakage limits given in Table AA.1 and Formula (AA.4), the orifice conductance G can be calculated for each of the *tidal volume* ranges. For example, the leakage limit for *tidal volumes* ≥300 ml is 200 ml/min at a pressure of 50 cmH_2O, which yields a value for G of 28,28 ml/(min·$hPa^{1/2}$). Conductance values for the other *tidal volume* ranges can be similarly calculated. Table AA.1 summarizes these results.

Table AA.1 — Calculated conductance values by *tidal volume* range

***Tidal volume* range** ml	**Leakage limit** ml/min	**Pressure, *P*** hPa (cmH_2O)	**Calculated conductance, *G*** ml/(min·$hPa^{1/2}$)
$V_{\text{tidal}} \le 50$	50	20	11,18
$50 \ge V_{\text{tidal}} \ge 300$	100	40	15,81
$V_{\text{tidal}} \ge 300$	200	50	28,28

Using these calculated conductances, it is then possible to find the corresponding *VBS* leakage limit at any pressure. Figure AA.3 demonstrates these relationships.

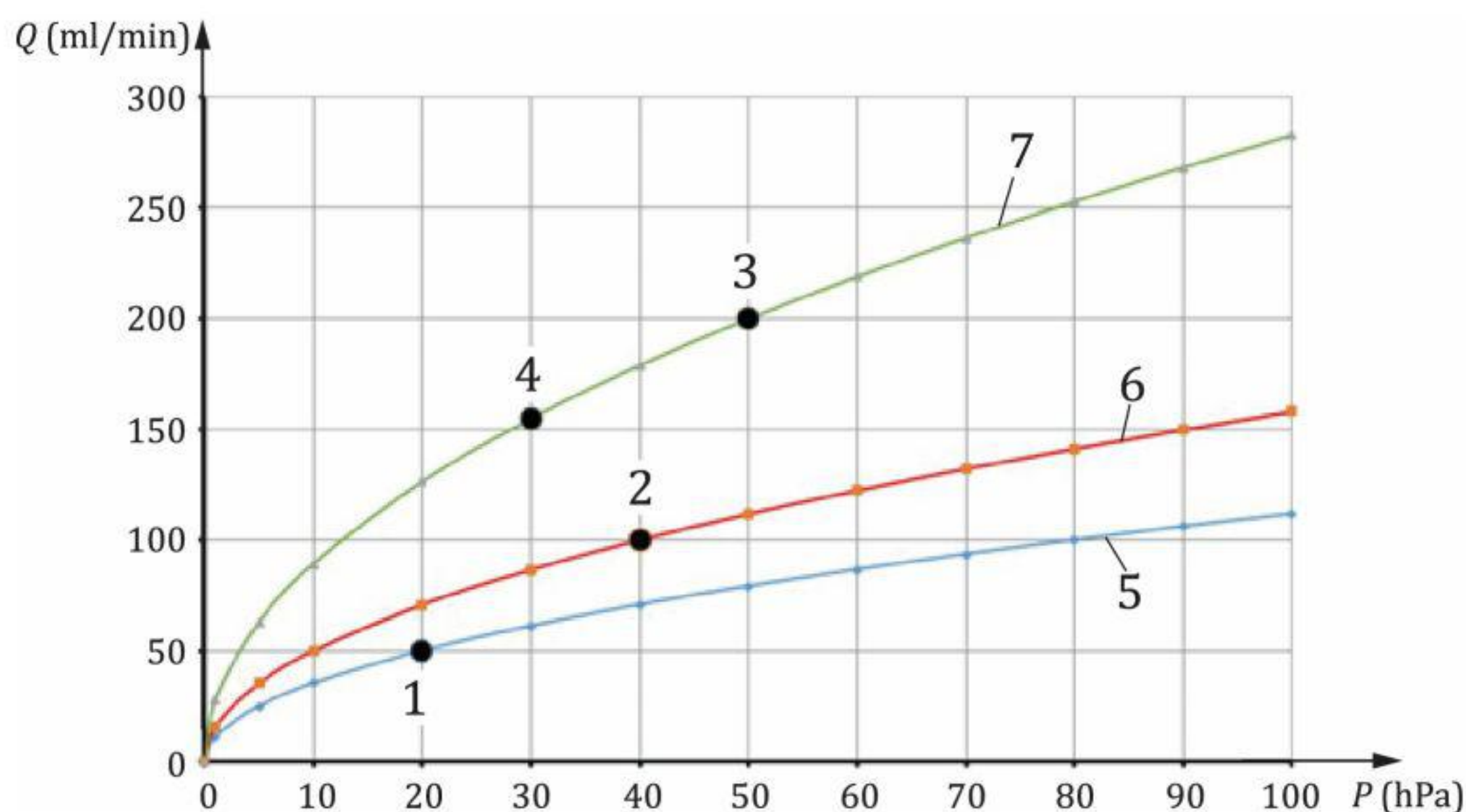
Using Figure AA.3, one can derive the 60 hPa (60 cmH_2O) *VBS* leakage flowrate limits. This is the pressure at which most of the *operator*-accessible parts of the *VBS* are specified for leakage flowrate.

— for $V_{\text{tidal}} \le 50$ ml, $Q_{\text{leak}} = 87$ ml/min

— for 50 ml $\ge V_{\text{tidal}} \ge 300$ ml, $Q_{\text{leak}} = 122$ ml/min

— for $V_{\text{tidal}} \ge 300$ ml, $Q_{\text{leak}} = 219$ ml/min

These leakage flowrate limits represent the permissible leakage of the entire *VBS*. It is common to allocate 90 % of the leakage flowrate to the *operator*-accessible parts of the *VBS* and 10 % to the parts of the *VBS* internal to the *ventilator*.

Q (ml/min)
300
250
200
150
100
50
0
0 10 20 30 40 50 60 70 80 90 100 P (hPa)
1 2 3 4 5 6 7

Key

1 leakage limit from ISO 80601-2-12 for $V_{tidal} \leq 50$ ml

2 leakage limit from ISO 80601-2-12 for 50 ml $\geq V_{tidal} \geq 300$ ml

3 leakage limit from ISO 80601-2-12 for $V_{tidal} \geq 300$ ml

4 leakage limit from ISO 80601-2-13[2]

A (blue) - Q_{leak} for $V_{tidal} \leq 50$ ml

B (red) - Q_{leak} for 50 ml $\geq V_{tidal} \geq 300$ ml

C (green) - Q_{leak} for $V_{tidal} \geq 300$ ml

NOTE This assumes leakage behaves as an orifice according to Formula (AA.4).

Figure AA.3 — *VBS* leakage flowrate limits as a function of pressure as specified in ISO 80601-2-12 and ISO 80601-2-13[2]

Subclause 201.102.7.2 — Non-invasive ventilation

The inaccuracies are due to the nature of the unintentional leaks (such as those that occur when a *patient's* mouth opens when on a nasal *mask* or when the *mask* seal begins leaking when the pressure inside reaches a certain pressure.

Subclause 201.103 — Spontaneous breathing during loss of power supply

Electrical or pneumatic power outside the values required for normal operation can affect all *ventilators* in a given unit. This is not limited to a loss of power but also includes excessive power. Although this is an infrequent event, it constitutes a particularly difficult situation because many or all *ventilators* can become simultaneously compromised. It is therefore imperative that such a *patient* can breathe spontaneously under these conditions until alternative ventilation is provided.

A previous version of this document (IEC 60601-2-12:2001) required disclosure of the resistance under failure conditions. Previous standards for critical care *ventilators* have required that the

pressure drop be less than 6 hPa (6 cmH_2O) at 60 l/min for adults. *Patients* in a critical care unit usually don't generate such high inspiratory flows. Considering this and that *accessories* can be placed in the *VBS*, the committee came to the conclusion that this value is unnecessarily design-restrictive. In addition, spontaneous breathing is only needed to bridge the time until alternative ventilation is provided. The committee came to the conclusion that a mere disclosure is not sufficient. The chosen values are regarded as more realistic and sufficient for this infrequent event and were tailored to the intended range of *tidal volumes*.

Subclause 201.104 — Indication of duration of operation

Ventilators require maintenance for continued safe use. A practicable means to ensure that this information is available to the *operator* or the *responsible organization* is to require that the *ventilator* keep track of how long it has been in operation.

Subclause 201.105.2 — Connection to electronic health record

Electronic documentation of *patient* care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual *patient* through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. In some countries, there is a governmental directive to provide electronic health records by 2015[52]. Electronic data transmission to the electronic health record is essential to meet this requirement. Annex BB contains information that *manufacturers* can find useful as requirements for data interfaces.

The data transmission should be capable of being provided with such a *functional connection* in accordance with ASTM F2761-09[26].

Subclause 201.105.3 — Connection to *distributed alarm system*

Patients who are *ventilator-dependent* are usually located in clinical environments that are staffed with *healthcare professional operators* in sufficiently close proximity to hear *alarm signals* coming from the *patient's* room. However, the layout of some critical care units is such that a *distributed alarm system* is needed to ensure that the *operator* can hear the *alarm signal*. *Patients* also can be in enclosed (positive or negative pressure) isolation rooms. In these settings, it can be difficult or impossible for *healthcare professional operators* to hear *alarm signals*. As a result, an appropriate response can be delayed with catastrophic results. A *distributed alarm system* facilitates delivery of *alarm signals* to remotely located *healthcare professional operators*, thereby permitting a timely response and intervention to support *patient* care[53].

The data transmission should be capable of being provided with a *functional connection* in accordance with ASTM F2761-09[26].

Subclause 201.107 — Timed ventilatory pause

Pausing artificial ventilation is necessary for certain clinical *procedures*.

EXAMPLE Chest x-ray at a *healthcare professional operator*-chosen level of *inflation*, chest x-ray at end-expiration, measuring central venous pressure or cardiac output, measuring respirophasic blood pressure variation, suctioning the airway, turning the *patient*.

Currently, in order to avoid nuisance *alarm signals* and to avoid cycling the *ventilator* while the *VBS* is disconnected from the *patient*, *healthcare professional operators* usually turn off the

ventilator and thereby incur the *risk* of undetected prolonged apnoea by subsequently forgetting to turn the *ventilator* back on.

Alternatively, the x-ray technicians manually attempt to synchronize chest x-ray exposure to ventilatory phase through hand-eye coordination, with varying effectiveness. Automated synchronization of x-ray exposure and ventilation would provide clinical benefits[54].

In addition, there are situations where, to permit the minimum disruption of ventilation, the initiation of the ventilatory pause needs to come from external equipment. This is particularly important for those *procedures*, e.g. high doses of radiation, where the *healthcare professional operator* needs to evacuate the immediate area or when manual synchronization would be less effective[54].

As part of the *risk management process*, special attention should be paid to ensuring that the *patient's* lungs remains adequately ventilated when either externally generated or repetitive ventilatory pauses occur.

The *expiratory pause* should be capable of being provided with a *functional connection* in accordance with ASTM F2761-09[26].

Subclause 202.4.3.1 — Compliance criteria

It is not the intent of the committee to require that the *immunity* tests be performed multiple times (e.g. with a *volume-control inflation-type* and *pressure-control inflation-type* at several *tidal volumes*), but that the *manufacturer* should determine which *inflation-type* and *tidal volume* represents the worst case for a given *immunity* test and use those conditions.

Subclause 202.8.101 — Additional general requirements

The committees recognized that during environmental stress (for example, shock, vibration, electromagnetic disturbances) *ventilator* performance can degrade. In such a situation, the duration of altered performance would be about minutes to, at most, few tens of minutes. Shock and drop disturbances can be even shorter (i.e. less than 100 ms). The question then became how to express the percent change in pressure and volume performance that would not cause *harm* to a *patient* during a brief interval of environmental stress. In today's intensive care unit (ICU) environment of Lung Protective Ventilation (LPV) in which according to clinical research, caution should be exercised when total lung pressures and *inflation* volumes encroach on pressures of 35 cmH_2O and volumes of 12 ml/kg, respectively. The committees examined various scenarios in which pressures and volumes exceed the above values. High-side deviations in the range of 5 % to 10 % offer little relief because the error of the monitoring falls in this same range. The issue, therefore, is what higher deviation is acceptable. The committees considered two situations:

1) an average of 25 % over 30 consecutive *inflation*s; and

2) a single *inflation* deviation of 35 %.

With respect to a total lung pressure of 35 cmH_2O and *tidal volume* of 12 ml/kg, the average values equal 43,8 cmH_2O and 15 ml/kg, respectively. Given that the maximum duration of a few tens of minutes (i.e., ≤30 min) a *patient* would be expected to tolerate these pressure and volume deviations without undue *risk*. The committees recognize that environmentally induced pressure and volume deviations would be uneven. Thus, maximum single deviations of 35 % yield values of 47,2 cmH_2O and 16,2 ml/kg. Although these values intrude into a range not recommended for

continuous ventilation, random values of this magnitude over a brief interval are not expected to create undue *harm*.

Subclause 206.102 — Training

The modern critical care *ventilator* is a complex life-sustaining *ME equipment* whose use requires specific training for each *manufacturer's* make and model. Different *manufacturers* often refer to similar *ventilation-modes* by different names, and, although in principle similar to another *manufacturer's ventilator*, their *ventilation-mode* is unique in sometimes minor and sometimes complex ways. It is essential, therefore, that however experienced the *operator*, every person involved with its operation and setup is fully trained in the *ventilator's* operational characteristics, in particular its controls, capabilities and limitations, prior to any use.

Subclause 208.6.8.4.101 — Additional requirements for termination of *alarm signal* inactivation

Permitting very long pauses of *alarm signals* can be hazardous for the *patient* since the *healthcare professional operator* will not be notified of the existence of an *alarm condition*. However, *patient* management often requires delicate *procedures* that can be disrupted by auditory *alarm signals*. Therefore, extending *audio paused* by *healthcare professional operator* action is useful to prevent the *ventilator* from disturbing the *healthcare professional operator* or others in the vicinity (e.g. surgeon or cardiologist) in the *patient's* room.

Ventilators should be equipped with an *audio paused* capability that permits the *healthcare professional operator* to pause the auditory *alarm signals* prior to the creation of an *alarm condition*. Such a capability permits the *healthcare professional operator* to minimize nuisance auditory *alarm signals* in situations that are known to be associated with creation of nuisance *alarm conditions*. A 'planned' disconnect is a common situation where this capability is needed. Examples include open suctioning, *breathing system filter* change, or insertion of a medication treatment. A closed suctioning *ventilator-operational mode* should also include such a capability.

Subclause 208.6.12.101 — Additional requirements for *alarm system* logging

Optimal management of a *patient* requires the capability to review the history of important *alarm conditions*. This is a more reasonable means of *risk control* in the critical care environment than *latching alarm signals*. Additional information is found in IEC 60601-1-8:2006+AMD1:2012, Annex A, for 6.12 – *alarm condition* logging.

Annex BB
(informative)

Data interfaces

BB.1 Background and purpose

Heightened interest in the monitoring of *ventilators*, as well as accountability and responsiveness of the parties involved, has become evident on an international scale. Consequently, *patients*, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of critical care *ventilators*. This trend is also driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the ventilatory performance of the *ventilator*, explicit criteria need be applied to choosing and defining parameters. This framework is intended to provide a common definition of parameters for *ventilators*. The selection is based on the agreement of the committees about what is to be monitored and for what purpose.

It is important to note that any data collection needs to be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted therapy indicators for *ventilators* not only fosters increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from *ventilators* is intended to help to eliminate the current shortcomings and significantly contribute to the improvement of the therapy. This approach seeks to provide a definition that can be used across ventilation therapy systems for providing therapy data independent of *ventilator manufacturer* or what mechanisms are used to transport the data, either locally or remotely to a *healthcare professional operator*. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a *patient* situation. It also provides for flexible and cost-effective integration into disparate systems that *healthcare professional operators* can use for *patient* data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet the needs of *patients*, caregivers, clinicians, service providers, and payers. As such, the definition of specific device communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this part of ISO 80601.

A number of monitoring requirements for *ventilators* require various types and levels of data (e.g. different levels of detail), depending on the needs of the *patient*, caregiver, clinician, service provider and payer. This part of ISO 80601 seeks to define the data that are required to meet the objectives of these users.

The following data are defined.

— **Parameters and units of measurement:** Parameters and units of measurement used in the *ventilator*

— **Equipment identification:** Information identifying the *ventilator*

— **Usage monitoring:** Temporal data relating to the use of the *ventilator*

— **Equipment settings:** The different *ventilation-modes* provided by *ventilators* that require different settings

— **Ventilation monitoring:** Information related to monitoring of *patient* ventilation

— ***Ventilator alarm limits*:** Settings relating to ventilation-related *alarm limits*

— **Event information:** Information provided about events related to the usage of the *ventilator*

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the *ventilator* and its *accessories*

All therapy systems should provide the information to enable identification of the *ventilator*. Implementation of any further data levels is optional.

Information identifying pressure units used in the data set should also be provided.

BB.2 Data definition

Table BB.101 defines information, which identifies units of measurement in the data set.

Table BB.101 — Parameters and units of measurement

Parameter	Description	Type
Pressure units	Specification of the units of measurement for pressure-related data	Value: (cmH_2O or hPa)
Flowrate units	Specification of the units of measurement for flowrate-related data	Value: (l/min or l/s)
Volume units	Specification of the units for volume-related data	Value: (ml or l)
Spontaneous breath rate	Specification of the units for *spontaneous breath rate*	Value: (breaths/min)
Set rate	Specification of the units for *set rate*	Value: (breaths/min)
Total respiratory rate	Specification of the units for *total respiratory rate*	Value: (breaths/min)
Inspiratory time units	Specification of the units for *inspiratory time*	Value: (s)
Expiratory time units	Specification of the units for expiratory time	Value: (s)
Leakage units	Specification of the units for leakage	Value: (ml/min or %)

Table BB.102 defines *ventilator* identification data.

Table BB.102 — Equipment identification

Parameter	Description	Type
Equipment *manufacturer*	Identification of the *manufacturer* of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment UDI	Unique device identifier (UDI)	Text string
Equipment serial number	Identification number of the equipment	Text string
Equipment software version	Identification of the software version(s) implemented in the equipment	Text string
NOTE More than one equipment identification can be needed to be communicated from the equipment.		

Table BB.103 defines data required for usage monitoring.

A set of measured and calculated values should be provided for each therapy session, where a therapy session is any period of time the *ventilator* is providing ventilation.

Table BB.103 — Usage monitoring

Parameter	Description	Type
Ventilation start date/time	The current UTC (coordinated universal time) date and time when the usage session was started	ISO 8601:2019[28] Date Time (YYYY-MM-DDThh:mm:ss)
Ventilation stop date/time	The current UTC (coordinated universal time) date and time when the usage session was stopped	ISO 8601:2019[28] Date Time (YYYY-MM-DDThh:mm:ss)
Hours of ventilation	Number of hours the equipment is powered on and providing ventilation (e.g. either to a *patient* or test lung) for the usage session	Value: (h)
Hours of *patient* use	Number of hours the equipment is providing therapy to the *patient* for the usage session	Value: (h)

Table BB.104 defines applicable current settings of the *ventilator* for each *ventilation-mode* of operation.

Table BB.104 — Equipment settings

Parameter	Description	Type
Ventilation-mode	*Ventilation-mode* systematic code as defined in ISO 19223:2019, Annex E — CMV-VC — CMV-PC — CMV-vtPC — A/C-VC — A/C-PC — A/C-vtPC — IMV-PC\PS — IMV-PC{S} — IMV-PC{S}\PS — IMV-PC\-\PS — IMV-vtPC\PS — SIMV-VC — SIMV-VC\PS — SIMV-PC\PS — SIMV-PC\PS\PS — SIMV-PC\PS(x2) — SIMV-PC\-\PS — SIMV-vtPC\PS — SIMV-PC{S}\PS — S/T-PS/VC — S/T-PS/PC(q) — S/T-vtPS/vtPC — CSV-PS — CSV-vtPS — CSV-ES — *CPAP*	Type selected
Patient category	*Patient* cohort classification (if applicable)	Type selected
Airway interface	Airway interface classification — invasive — non-invasive	Type selected
Breathing system	Breathing system classification (if applicable) — single limb with leak port — single limb with controlled expiratory valve — dual limb with controlled expiratory valve — other	Type selected
Language	Identification of the user interface language setting according to ISO 639-1:2002[1]	Value: (2-letter alpha)
Display brightness	Setting of the luminous intensity as a percentage of the maximum setting	Decimal value (2-digit %)
Δ inspiratory pressure	Setting of the *airway pressure*, as a difference above *BAP*, during an *inflation phase* (if applicable to *ventilation-mode*)	Decimal value: (cmH_2O or hPa)
BAP	Reference *airway-pressure* level that can be above the ambient pressure by a set amount and at which a *patient* breathes when unassisted and upon which *inflations* are superimposed	Decimal value: (cmH_2O or hPa)

Parameter	Description	Type
Inflation initiation means	Parameter(s) used to determine initiation of an *inflation* (*ventilator* inspiration) — *patient*-triggered event — timed event — manual input — conditional termination of an *expiratory phase* — signal from a remote device	Type selected
Trigger class	Function that detects that the measured value(s) of a parameter(s) that can be attributed to the *patient* has reached the threshold value required to initiate another event — Flow trigger — pressure trigger — EMG (electromyograph) trigger	Type selected
Trigger level	Set threshold value for a trigger function	Decimal value
Inflation termination means	Parameters used to determine termination of an *inflation* (*ventilator* inspiration) (where applicable) — time — flow — pressure — effort — volume-	Type selected
Termination level	Set threshold value at which termination is intended to occur (if applicable) (units depend on termination mode) or % of peak flow	Decimal value
Tidal volume	Setting for the volume of gas intended to enter the lung during a *respiratory cycle*	Decimal value: (ml)
Inspiratory flow waveform	Intended flow waveform for a flow-regulated *inflation*-type (*ventilator* inspiration) — constant flow — decreasing flow pattern	Type selected
Rise time	Set indication of the time for the regulated parameter to rise to a set value following the initiation of an *inflation*	Decimal value
Set rate	Setting for the number of *inflations* (*ventilator* inspirations) that are assured to occur in a specified period of time	Decimal value: (breaths/min)
I:E ratio	Set ratio of the duration of the *inspiratory time* to the duration of the expiratory time	Value: (I:E)
Inspiratory time	Set duration for an *inflation* (*ventilator* inspiration) (if terminated by time)	Decimal value: (s)
Pressure limit	Set *airway-pressure* threshold value for the initiation of an action to protect the *patient* during *normal condition*	Decimal value: (cmH_2O or hPa)

Parameter	Description	Type
Volume limit	Setting used to determine the maximum *tidal volume* that can be provided during an *inflation* (*ventilator* inspiration)	Decimal value (ml)
Sigh	Activation of sigh function	Function selected: (yes/ no)
Sigh period	Set duration for a sigh *inflation* (if terminated by time)	Decimal value: (s)
Sigh frequency	Set initiation frequency for a sigh *inflation*	Decimal value: (breaths/min)
Apnoea limit	Duration of *patient* apnoea after which an *inflation*, of a predetermined type, is provided	Decimal value: (s)
Apnoea frequency	Set frequency at which preset *inflations* are provided during periods of *patient* apnoea	Decimal value: (breaths/min)
Apnoea volume	The set volume intended to be delivered in a *inflation* (*ventilator* inspiration) during apnoea ventilation (if applicable)	Decimal value: (ml)
Apnoea *Δ inspiratory pressure*	Setting of the *airway pressure*, as a difference above baseline *airway pressure*, during an apnoea *inflation* (*ventilator* inspiration) (if applicable)	Decimal value: (cmH_2O or hPa)
Oxygen concentration	Set fraction of oxygen in the delivered gas	Decimal value: (%)
Oxygen measurement	Activation of O_2 monitoring	Function selected: (yes/ no)
Expired volume measurement	Activation of expired volume monitoring (if applicable)	Function selected: (yes/ no)
Expired CO_2 measurement	Activation of expired CO_2 monitoring (if applicable)	Function selected: (yes/ no)

Table BB.105 defines the indicators relating to monitoring of *patient* ventilation.

Table BB.105 — Ventilation monitoring

Parameter	Description	Type
Peak inspiratory pressure	Highest *airway pressure* reached during a previous *respiratory cycle*	Decimal value: (cmH_2O or hPa)
PEEP	Measured expiratory pressure at the end of an *expiratory phase*	Decimal value: (cmH_2O or hPa)
Mean *airway pressure*	Mean *airway pressure* over a full *respiratory cycle*	Decimal value: (cmH_2O or hPa)
O_2	Fraction of oxygen in the delivered gas	Decimal value: (% O_2 V/V)
Inspiratory volume	Volume of gas delivered through the *patient-connection port* during an *inflation*	Decimal value: (ml)
Expired volume	Volume of gas leaving the lungs through the *patient-connection port* during an *expiratory phase*	Decimal value: (ml)
End tidal CO_2	End-expiratory level of CO_2 leaving the lungs through the *patient-connection port* during an *expiratory phase*	Decimal value: (kPa or mmHg)
Inspiratory minute volume	Volume of gas passing through the *patient-connection port* during inspiratory or *inflation* phases, expressed as a volume per minute	Decimal value: (l/min)
Expired minute volume	Volume of gas leaving the lungs through the *patient-connection port* during *expiratory phases*, expressed as a volume per minute	Decimal value: (l/min)
Assured inflation-type rate	Number of *inflations* (*ventilator* inspirations) initiated in a specified time, expressed as breaths per minute	Decimal value: (breaths/min)
Spontaneous breath rate	Number of spontaneous breaths initiated in specified time, expressed as breaths per minute	Decimal value: (breaths/min)
Total respiratory rate	Number of *respiratory cycles* initiated in a specified time, expressed as breaths per minute (spontaneous breaths plus *ventilator inflations*)	Decimal value: (breaths/min)
Low respiratory rate	Lowest rate of ventilatory breathing cycles delivered by the *ventilator*	Decimal value: (cycles/min)
I:E ratio	Ratio of the duration of the *inspiratory time* to the duration of the expiratory time	Value: (I:E)
Total leakage	Loss of respiratory gas from the *VBS* and the *patient* during the *respiratory cycle*	Value: (ml/min or %)

Table BB.106 defines the applicable current *alarm limits* of the *ventilator*.

Table BB.106 — *Ventilator alarm limits*

Parameter	Description	Type
High *airway pressure alarm condition*	Setting of the *alarm limit* for high pressure during the *respiratory cycle*	Value: (cmH_2O or hPa)
High FiO_2 *alarm condition*	Setting of the *alarm limit* for high inspiratory oxygen concentration	Value: (% O_2 V/V)
Low FiO_2 *alarm condition*	Setting of the *alarm limit* for low inspiratory oxygen concentration	Value: (% O_2 V/V)
High end-expiratory CO_2 *alarm condition*	Setting of the *alarm limit* for high end-expiratory CO_2 concentration	Value: (% CO_2 V/V)
Low end-expiratory CO_2 *alarm condition*	Setting of the *alarm limit* for low end-expiratory CO_2 concentration	Value: (% CO_2 V/V)
High inspiratory *tidal volume alarm condition*	Setting of the *alarm limit* for high inspiratory *tidal volume* delivered by the *ventilator*	Value: (ml)
Low inspiratory *tidal volume alarm condition*	Setting of the *alarm limit* for low inspiratory *tidal volume* delivered by the *ventilator*	Value: (ml)
High expiratory *tidal volume alarm condition*	Setting of the *alarm limit* for high expiratory *tidal volume*	Value: (ml)
Low expiratory *tidal volume alarm condition*	Setting of the *alarm limit* for low expiratory *tidal volume*	Value: (ml)
High inspiratory minute volume *alarm condition*	Setting of the *alarm limit* for high inspiratory minute volume delivered by the *ventilator*	Value: (ml/min or l/min)
Low inspiratory minute volume *alarm condition*	Setting of the *alarm limit* for low inspiratory minute volume delivered by the *ventilator*	Value: (ml/min or l/min)
High expiratory minute volume *alarm condition*	Setting of the *alarm limit* for high expiratory minute volume	Value: (ml/min or l/min)
Low expiratory minute volume *alarm condition*	Setting of the *alarm limit* for low expiratory minute volume	Value: (ml/min or l/min)
High respiratory rate *alarm condition*	Setting of the *alarm limit* for high rate of respiratory breathing cycles delivered by the *ventilator*	Value: (breaths/min)
Low respiratory rate *alarm condition*	Setting of the *alarm limit* for low rate of respiratory breathing cycles delivered by the *ventilator*	Value: (breaths/min)
Leak *alarm condition*	Setting of the *alarm limit* for high unintentional leak	Value: (l/min or %)

Table BB.107 defines applicable *ventilator* usage information.

Table BB.107 — Event information

Parameter	Description	Type
Power supply source	Current source of electrical power — external AC *supply mains* — *internal electrical power source* — external DC *supply mains*	Type in use
Alarm signal inactive state present	List of text strings (*alarm off, alarm pause, audio off, audio pause, acknowledged*)	List of text strings
Active *alarm condition*	Currently active *alarm conditions*	List of text strings (*manufacturer*-defined)
Access mode	Current access mode of the *ventilator* — supervising clinician or the *healthcare professional operator* — *responsible organization*	Type in use

Table BB.108 defines applicable service and maintenance parameters.

Table BB.108 —Service monitoring

Parameter	Description	Type
Maintenance needed	A *manufacturer*-specific list of any items requiring maintenance, e.g. *mask*, tubing, filter	List of text strings (*manufacturer*-defined)
Ventilator service indicator	An indication that service is required	Text string: (*manufacturer*-defined)
Hours of ventilation	Number of hours the equipment is powered on and providing ventilation	Value: (h)
Hours until next scheduled maintenance	The next *manufacturer*-specified suggested maintenance interval	Value: (h)

Annex CC
(informative)

Reference to the essential principles

This document has been prepared to support the *essential principles of safety and performance* of a *ventilator*, its *accessories* or parts as medical devices according to ISO 16142-1:2016. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of ISO 16142-1:2016. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the *essential principles* of ISO 16142-1:2016.

Table CC.1 — Correspondence between this document and the *essential principles*

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
1	All	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2	201.4	The part relating to manufacturing is not addressed.
a)	All	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.7, 201.11, 201.12, 201.13, 208	
d)	201.7	
3	All	The part relating to manufacturing is not addressed.
4	All	
5	201.4, 201.15	
6	201.4	
8.1	201.11	
a)	201.11	
b)	201.4, 201.11	
c)	201.9, 201.15	
8.2	201.11	
8.3	201.11	
8.4	201.11	
8.5	201.11	
9.1	201.11, 201.13.2.101 c)	
9.8	201.7.2.17.101 b)	

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
12.1	201.7, 201.14, 201.16, 201.101, 201.102	
12.2	—	
a)	201.9, 201.11, 206, 208	
b)	206, 208	
c)	202	
d)	201.11	
e)	201.11	
f)	201.14, 201.16, 201.105	
g)	201.11, 202	
12.4	201.11	
12.5	201.7, 201.8	
12.6	201.1.3	
13.1	201.12.1, 201.102	
13.2	201.7, 201.12.1	
13.3	201.7, 201.12.4, 201.102, 206, 208	
13.4	201.7.4.3	
14.1	201.10	
14.3	201.10	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13	
16.3	201.11.8.101	
16.4	201.11.8.101, 201.12.4, 201.13.101, 208	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9	
17.2	201.9	
17.3	201.9	
17.4	201.15	
17.5	201.9, 201.101	
17.6	201.11	
18.1	201.12.1	
18.2	201.12.4	
19.1	201.7, 201.102, 206	
19.2	201.7, 201.102, 206	

Essential principle of ISO 16142-1:2016, Annex B	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7	
21.5	—	
a)	201.7	The part relating to authorized representative is not addressed
b)	201.7.2.17.101 a) 1)	
d)	201.7.2.17.101 a) 2)	
e)	201.7	
f)	201.7.2.17.101 b)	
i)	201.7.2.101 a) 1)	
j)	201.7.2.101 a) 1)	
k)	201.7.2.101 a) 2)	
l)	201.7	
21.6	201.7, 201.7.2.17.101 a) 2)	
21.7	—	
a)	201.7.9.1	
b)	201.7	
d)	201.7.2.17.101 b), 201.7.9.2.1.101 a)	
g)	201.7.9.2.9.101 f)	
i)	201.7.9.2.2.101	
k)	201.7.9.2.8.101, 201.7.9.2.9.101, 201.7.9.2.14.101, 201.16, 201.102.2	
l)	201.7.9.2.8.101, 201.7.9.2.9.101	
n)	201.16	
p)	201.7.9.2.12, 201.11	
q)	201.7	
21.8	201.7	

Annex DD
(informative)

Reference to the general safety and performance requirements

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745[55]. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific general safety and performance requirements of regulation (EU) 2017/745[55]. Other means are possible. Table DD.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745.

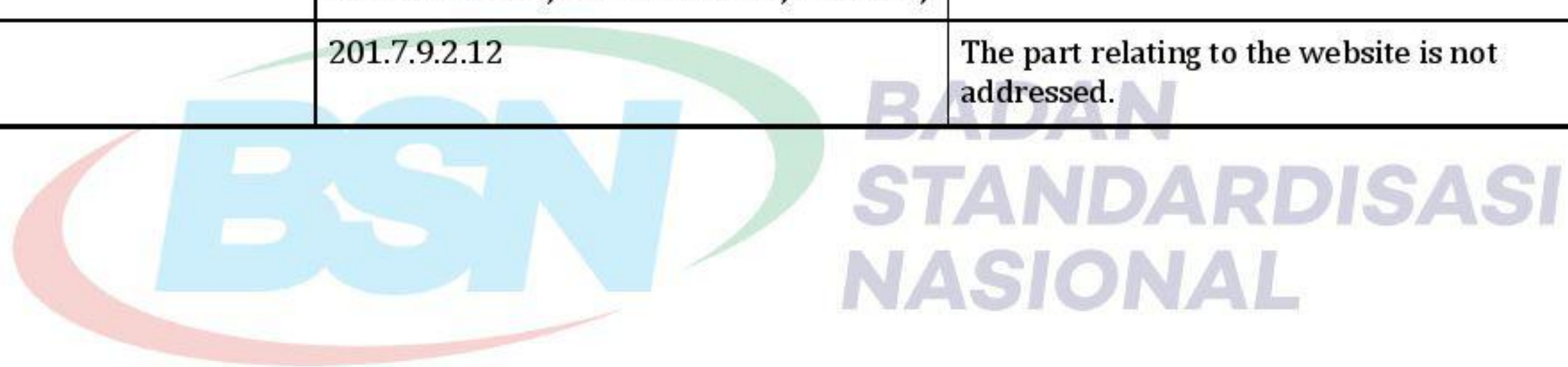
Where a reference from a clause or subclause of this document to the *risk management process* is made, the *risk management process* shall be such that *risks* have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding general safety and performance requirement.

NOTE When a general safety and performance requirement does not appear in Table DD.1, it means that it is not addressed by this document.

Table DD.1 — Correspondence between this document and the general safety and performance requirements

General safety and performance requirements of regulation (EU) 2017/745, Annex I[55]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
5 a)	201.12.1, 206	
5 b)	206	
10.1	201.7.2.13.101, 201.11.6.6, 201.11.7	Only the part relating to design is addressed.
10.2	201.11.6.6, 201.11.7	Only the part relating to design is addressed.
10.3	201.11.6.6, 201.11.7	Only the part relating to design is addressed.
10.4	201.11.7, 201.101.2.2, 201.102.6	Only the part relating to design is addressed.
10.5	201.11	Only the part relating to design is addressed.
10.6	201.11.7, 201.101.2.2, 201.102.6	Only the part relating to design is addressed.
11.1 b)	201.11.6.6	Only the part relating to design is addressed.
11.1 c)	201.11.6.6, 201.11.6.7	
11.1 d)	201.101.2.2	
11.2	201.11.6.6	
11.7	201.7.2.17.101	
14.1	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.14.101, 201.16.1.101. 201.101, 201.101.2, 201.12.4.101, 201.12.4.104	

General safety and performance requirements of regulation (EU) 2017/745, Annex I[55]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
14.2 a)	201.9, 201.12.1, 201.12.4, 206	Only the part relating to design is addressed.
14.2 b)	202	Only the part relating to design is addressed.
14.2 f)	202	Only the part relating to design is addressed.
14.3	201.11	Only the part relating to design is addressed.
14.5	201.7.2.4.101, 201.7.9.2.14.101, , 201.7.9.3.1.101, 201.12.4.101, 201.12.4.104, 201.16.1.101, 201.101, 201.102	
14.6	201.12.1	
15.1	201.12.1.101, 201.12.2.102, 201.12.1.103	The part relating to stability is not addressed.
17.1	201.14.101	
17.2	201.14.101	
18.1	201.13	
18.2	201.11.8.101.1	
18.3	201.11.8.101.1	
18.4	201.12.4	
18.5	202	
18.6	202	
18.7	201.9.6.2.1.101	
20.3	201.9.6.2.1.101	Only the part relating to design is addressed.
20.5	201.101.3, 201.101.3.2.4	Only the part relating to design is addressed.
20.6	201.11.1.2.2	
21.1	201.12.1, 201.12.1.101, 201.12.1.102, 201.12.1.103	Only the protection of the *patient* is covered.
21.2	201.12.4.105, 201.12.4.106, 201.12.4.107, 201.12.4.108, 201.12.4.109, 201.12.101, 201.13	Only the first sentence is covered.
21.3	201.7.1.2, 201.12.1, 206	
23.1	201.7, 201.7.2.101, 201.7.9.2.1.101, 201.7.9.2.2.101	The part relating to the website is not addressed.
23.1 a)	201.7.9.2.1.101, 206	
23.1 b)	201.7.2.101	
23.1 g)	201.7.9.2.1.101, 201.7.9.2.2.101	
23.1 h)	201.7.3, 201.7.2.13.101, 201.7.2.17.101, 201.11.7	
23.2 b)	201.7.2.17.101 a) 1)	The part relating to intended purpose is not addressed.
23.2 c)	201.7.9.1	
23.2 d)	201.7.9.1	

General safety and performance requirements of regulation (EU) 2017/745, Annex I[55]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
23.2 g)	201.7.2.17.101 a) 2)	
23.2 k)	201.7.2.101 a) 1)	
23.2 m)	201.7.2.3, 201.7.2.13.101, 201.7.2.101, 201.7.9.2.2.101	
23.4 a)	201.7.9.1	
23.4 e)	201.7.9.2.9.101	
23.4 f)	201.7.9.2.9.101, 201.7.9.2.14.101	
23.4 g)	201.7.9.2.2.101	
23.4 h)	201.7.9.2.8.101, 201.7.9.2.9.101	
23.4 k)	201.7.9.2.8.101	
23.4 n)	201.4.4, 201.7.9.2.12, 201.11.6.6, 201.104	
23.4 q)	201.7.9.2.8.101, 201.7.9.2.14.101	
23.4 s)	201.7.9.2.2.101, 201.7.9.2.2.101, 201.7.9.2.8.101, 201.7.9.2.9.101, 201.11.7,	
23.4 v)	201.7.9.2.12	The part relating to the website is not addressed.

Annex EE
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) and the IEC Electropedia (see 201.3) provide access to many of these terms and definitions.

Term	Source
accessory	IEC 60601-1:2005, 3.3
accompanying document	IEC 60601-1:2005, 3.4
acknowledged	IEC 60601-1-8:2006+AMD1:2012, 3.37
airway pressure (P_{aw})	ISO 19223:2019, 3.6.1
alarm condition	IEC 60601-1-8:2006+AMD1:2012, 3.1
alarm condition delay	IEC 60601-1-8:2006, 3.2
alarm limit	IEC 60601-1-8:2006, 3.3
alarm off	IEC 60601-1-8:2006, 3.4
alarm paused	IEC 60601-1-8:2006, 3.5
alarm settings	IEC 60601-1-8:2006, 3.8
alarm signal	IEC 60601-1-8:2006, 3.9
alarm system	IEC 60601-1-8:2006, 3.11
applied part	IEC 60601-1:2005, 3.8
assured inflation-type rate	ISO 19223:2019, 3.5.2.1
audio off	IEC 60601-1-8:2006, 3.12
audio paused	IEC 60601-1-8:2006, 3.13
BAP	ISO 19223:2019, 3.10.2
basic safety	IEC 60601-1:2005, 3.10
bias flow	ISO 19223:2019, 3.7.7
biocompatibility	ISO 18562-1:2017, 3.3
breathing system filter	ISO 23328-2:2002, 3.1
BSF	ISO 23328-2:2002, 3.1
BTPS	IEC 80601-2-74:2017, 201.3.203
cleaning	ISO 17664:2017, 3.1
clearly legible	IEC 60601-1:2005+AMD1:2012, 3.15
continuous flow	ISO 19223:2019, 3.7.8
continuous operation	IEC 60601-1:2005, 3.18
continuous positive airway pressure	ISO 19223:2019, 3.11.15
CPAP	ISO 19223:2019, 3.11.15
Δ inspiratory pressure	ISO 19223:2019, 3.6.7
disinfection	ISO 17664:2017, 3.3

Term	Source
distributed alarm system	IEC 60601-1-8:2006, 3.17
emergency intake port	201.3.201
emergency medical services environment	IEC 60601-1-12:2014, 3.1
enclosure	IEC 60601-1:2005, 3.26
end-expiratory flow	ISO 19223:2019, 3.7.6
essential performance	IEC 60601-1:2005+AMD1:2012, 3.27
essential principles	ISO 16142-1:2016, 3.3
essential principles of safety and performance	ISO 16142-1:2016, 3.3
exhaust port	ISO 19223:2019, 3.14.2
expected service life	IEC 60601-1:2005+AMD1:2012, 3.28
expiratory pause	ISO 19223:2019, 3.4.4
expiratory phase	ISO 19223:2019, 3.4.2
false positive alarm condition	IEC 60601-1-8:2006, 3.21
flow-direction-sensitive component	201.3.202
fresh gas	201.3.203
functional connection	IEC 60601-1:2005, 3.33
gas intake port	201.3.204
gas output port	ISO 19223:2019, 3.14.3
gas pathway	ISO 18562-1:2017, 3.7
gas return port	ISO 19223:2019, 3.14.4
harm	IEC 60601-1:2005+AMD1:2012, 3.38
hazard	IEC 60601-1:2005+AMD1:2012, 3.39
hazardous situation	IEC 60601-1:2005+AMD1:2012, 3.40
healthcare professional	201.3.205
heat and moisture exchanger	ISO 9360-1:2000, 3.1
high priority	IEC 60601-1-8:2006, 3.22
high-pressure input port	201.3.206
HME	ISO 9360-1:2000, 3.1
home healthcare environment	IEC 60601-1-11:2015, 3.1
humidifier	IEC 80601-2-74:2017, 201.3.208
I:E ratio	ISO 19223:2019, 3.4.19
immunity	IEC 60601-1-2:2014, 3.8
inflation	ISO 19223:2019, 3.3.1
inflation phase	ISO 19223:2019, 3.4.10
inflation-type	ISO 19223:2019, 3.3.2

Term	Source
information signal	IEC 60601-1-8:2006, 3.23
inspiratory pause	ISO 19223:2019, 3.4.12
inspiratory time (t_I)	ISO 19223:2019, 3.4.8
inspiratory volume (V_{insp})	ISO 19223:2019, 3.8.3
intended use	IEC 60601-1:2005+AMD1:2012, 3.44
intelligent alarm system	IEC 60601-1-8:2006, 3.24
internal electrical power source	IEC 60601-1:2005, 3.45
latching alarm signal	IEC 60601-1-8:2006, 3.26
low priority	IEC 60601-1-8:2006, 3.27
manufacturer	IEC 60601-1:2005+AMD1:2012, 3.55
mask	ISO 17510:2015, 3.4
maximum limited pressure ($P_{LIM\ max}$)	ISO 19223:2019, 3.13.3
maximum working pressure ($P_{W\ max}$)	ISO 19223:2019, 3.13.4
ME equipment	IEC 60601-1:2005, 3.63
ME system	IEC 60601-1:2005, 3.64
mechanical hazard	IEC 60601-1:2005, 3.61
medical electrical equipment	IEC 60601-1:2005, 3.63
medical electrical system	IEC 60601-1:2005, 3.64
medical gas pipeline system	ISO 7396-1:2016, 3.36
medium priority	IEC 60601-1-8:2006, 3.28
minimum limited pressure ($P_{LIM\ min}$)	201.3.207
model or type reference	IEC 60601-1:2005, 3.66
monitoring equipment	201.3.208
nominal <value>	IEC 60601-1:2005, 3.69
normal condition	IEC 60601-1:2005, 3.70
normal use	IEC 60601-1:2005, 3.71
operator	IEC 60601-1:2005, 3.73
operator-equipment interface	IEC 60601-1-6:2010, 3.1
operator's position	IEC 60601-1-8:2006, 3.30
patient	IEC 60601-1:2005+AMD1:2012, 3.76
patient-connection port	ISO 19223:2019, 3.14.5
PEEP	ISO 19223:2019, 3.10.4
PEMS	IEC 60601-1:2005, 3.90

Term	Source
PESS	IEC 60601-1:2005, 3.91
physiologic closed-loop control system	IEC 60601-1-10:2007, 3.19
positive end-expiratory pressure	ISO 19223:2019, 3.10.4
pressure-control	ISO 19223:2019, 3.3.4
primary operating function	IEC 62366-1:2015, 3.11
procedure	IEC 60601-1:2005+AMD1:2012, 3.88
process	IEC 60601-1:2005+AMD1:2012, 3.89
processing	ISO 17664:2017, 3.8
professional healthcare facility	201.3.209
programmable electrical medical systems	IEC 60601-1:2005, 3.90
programmable electronic subsystem	IEC 60601-1:2005, 3.91
protection device	201.3.210
rated <value>	IEC 60601-1:2005, 3.97
residual risk	IEC 60601-1:2005+AMD1:2012, 3.100
respiratory cycle	ISO 19223:2019, 3.4.16
responsible organization	IEC 60601-1:2005, 3.101
risk	IEC 60601-1:2005+AMD1:2012, 3.102
risk control	IEC 60601-1:2005+AMD1:2012, 3.105
risk management	IEC 60601-1:2005+AMD1:2012, 3.107
risk management file	IEC 60601-1:2005+AMD1:2012, 3.108
safety sign	ISO 7010:2019, 3.3
service personnel	IEC 60601-1:2005, 3.113
set rate	ISO 19223:2019, 3.5.1.1
single fault condition	IEC 60601-1:2005+AMD1:2012, 3.116
single fault safe	IEC 60601-1:2005, 3.117
software item	IEC 62304:2006+AMD1:2015, 3.25
spontaneous breath rate	ISO 19223:2019, 3.5.1.3
stationary	IEC 60601-1:2005+AMD1:2012, 3.118
sterilization	ISO 17664:2017, 3.17
STPD	IEC 80601-2-74:2017, 201.3.220
suction catheter	ISO 8836:2014, 3.22
supply mains	IEC 60601-1:2005, 3.120
technical alarm condition	IEC 60601-1-8:2006, 3.36
tidal volume (V_{tidal})	ISO 19223:2019, 3.8.1
tool	IEC 60601-1:2005, 3.127

Term	Source
total respiratory rate	ISO 19223:2019, 3.5.1.2
transit-operable	IEC 60601-1-11:2015, 3.4
type test	IEC 60601-1:2005, 3.135
usability	IEC 62366-1:2015, 3.16
usability engineering	IEC 62366-1:2015, 3.17
usability engineering file	IEC 62366-1:2015, 3.18
validated	ISO 9000:2015, 3.8.13
VBS	ISO 19223:2019, 3.1.18
ventilator	ISO 19223:2019, 3.1.1
ventilator breathing system	ISO 19223:2019, 3.1.18
ventilator operational-mode	ISO 19223:2019, 3.11.1
ventilation-mode	ISO 19223:2019, 3.11.2
ventilator-dependent	201.3.211
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volume-control	ISO 19223:2019, 3.3.3

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